TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 1 of 2)

Lab: Harrogate
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2763.260, 2763.260	2763.260, 2763.260	3.000, 3.000	1.085, 0.955	1.723, 1.399
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.7283, 0.5150	1.2197, 0.7042
	MEDIAN	NA	2763.260	2763.260	3.000	1.085	1.600
	MIN, MAX	NA, NA	2763.264, 2763.264	2763.264, 2763.264	3.000, 3.000	0.570, 1.600	0.570, 3.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.570, 1.600	0.570, 3.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2338.360, 1614.220	2471.970, 1584.900	2419.690, 1596.310	8.960, 2.928	2.418, 2.092	5.421, 2.442
	SD, SE	1411.7400, 332.7500	2007.3300, 379.3500	1781.8200, 262.7160	19.7467, 3.7318	1.5197, 0.2645	13.6933, 1.7532
	MEDIAN	2319.820	1879.750	2032.230	2.018	1.980	1.995
	MIN, MAX	22.137, 4893.750	116.325, 6337.875	22.137, 6337.875	0.530, 88.160	0.800, 7.776	0.530, 88.160
	5%, 95%	22.137, 4893.750	152.361, 6081.580	152.361, 5830.270	0.650, 63.054	0.960, 6.825	0.950, 17.248
	BLQ Values Included	0	0	0	13	26	39
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.370, 1.370	1.370, 1.370
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.370	1.370
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.370, 1.370	1.370, 1.370
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1780.890, 967.177	1780.890, 967.177	0.810, 0.810	NA, NA	0.810, 0.810
	SD, SE	NA, NA	2163.7100, 1249.2200	2163.7100, 1249.2200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	828.948	828.948	0.810	NA	0.810
	MIN, MAX	NA, NA	256.360, 4257.365	256.360, 4257.365	0.810, 0.810	NA, NA	0.810, 0.810
	5%, 95%	NA, NA	256.360, 4257.370	256.360, 4257.370	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 2 of 7)

Lab: Harrogate
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3200.630, 3200.630	3200.630, 3200.630	2.750, 2.750	0.950, 0.905	1.550, 1.310
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4101, 0.2900	1.0789, 0.6229
	MEDIAN	NA	3200.630	3200.630	2.750	0.950	1.240
	MIN, MAX	NA, NA	3200.626, 3200.626	3200.626, 3200.626	2.750, 2.750	0.660, 1.240	0.660, 2.750
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.660, 1.240	0.660, 2.750
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	2363.200, 1645.410	2610.920, 1848.080	2511.830, 1764.180	15.481, 2.628	2.497, 2.179	8.457, 2.375
	SD, SE	1282.6200, 302.3160	2080.6700, 400.4240	1791.3200, 267.0340	65.3511, 12.3502	1.4209, 0.2473	44.3338, 5.6764
	MEDIAN	2157.760	2081.690	2099.050	1.680	2.200	2.150
	MIN, MAX	10.710, 4608.540	192.780, 9552.459	10.710, 9552.459	0.625, 348.555	0.750, 7.128	0.625, 348.555
	5%, 95%	10.710, 4608.540	232.320, 5810.680	232.320, 5420.360	0.815, 14.926	0.915, 6.160	0.820, 7.128
	BLQ Values Included	0	0	0	17	30	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.340, 2.340	2.340, 2.340
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.340	2.340
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.340, 2.340	2.340, 2.340
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2198.580, 744.317	2198.580, 744.317	1.525, 1.525	NA, NA	1.525, 1.525
	SD, SE	NA, NA	3285.3200, 1896.7800	3285.3200, 1896.7800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	457.045	457.045	1.525	NA	1.525
	MIN, MAX	NA, NA	150.672, 5988.015	150.672, 5988.015	1.525, 1.525	NA, NA	1.525, 1.525
	5%, 95%	NA, NA	150.672, 5988.020	150.672, 5988.020	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 3 of 7)

Lab: Harrogate
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4888.240, 4888.240	4888.240, 4888.240	2.910, 2.910	1.559, 1.480	2.009, 1.854
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.6944, 0.4910	0.9217, 0.5321
	MEDIAN	NA	4888.240	4888.240	2.910	1.559	2.050
	MIN, MAX	NA, NA	4888.236, 4888.236	4888.236, 4888.236	2.910, 2.910	1.068, 2.050	1.068, 2.910
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.068, 2.050	1.068, 2.910
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	2835.840, 1478.690	2788.460, 2244.740	2807.630, 1895.780	3.528, 2.502	2.239, 2.082	2.831, 2.265
	SD, SE	2590.2600, 628.2300	1501.9000, 300.3810	1984.7700, 306.2560	3.8864, 0.7345	0.8688, 0.1512	2.7602, 0.3534
	MEDIAN	1851.270	2468.420	2379.190	2.125	2.050	2.100
	MIN, MAX	10.061, 7734.320	95.232, 5749.170	10.061, 7734.320	0.750, 19.760	0.940, 4.740	0.750, 19.760
	5%, 95%	10.061, 7734.320	837.200, 5508.020	288.769, 7314.620	0.750, 8.410	0.990, 3.948	0.990, 7.224
	BLQ Values Included	0	0	0	17	31	48
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.429, 2.429	2.429, 2.429
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.429	2.429
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.429, 2.429	2.429, 2.429
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1037.780, 766.204	1037.780, 766.204	1.430, 1.430	NA, NA	1.430, 1.430
	SD, SE	NA, NA	1014.2800, 585.5930	1014.2800, 585.5930	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	484.968	484.968	1.430	NA	1.430
	MIN, MAX	NA, NA	420.000, 2208.362	420.000, 2208.362	1.430, 1.430	NA, NA	1.430, 1.430
	5%, 95%	NA, NA	420.000, 2208.360	420.000, 2208.360	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 4 of ?)

Lab: Harrogate
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3617.380, 3617.380	3617.380, 3617.380	2.887, 2.887	1.198, 1.193	1.761, 1.602
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.1485, 0.1050	0.9808, 0.5663
	MEDIAN	NA	3617.380	3617.380	2.887	1.198	1.303
	MIN, MAX	NA, NA	3617.380, 3617.380	3617.380, 3617.380	2.887, 2.887	1.093, 1.303	1.093, 2.887
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.093, 1.303	1.093, 2.887
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2520.490, 1688.990	2531.320, 1843.960	2527.090, 1781.690	9.323, 3.103	2.385, 2.171	5.570, 2.558
	SD, SE	1535.5400, 361.9290	1745.0200, 329.7770	1648.5800, 243.0700	26.0718, 4.9271	1.0449, 0.1819	17.8499, 2.2854
	MEDIAN	2405.250	1934.390	2046.090	1.953	2.223	2.193
	MIN, MAX	14.303, 5334.180	162.499, 6909.320	14.303, 6909.320	0.977, 138.186	0.967, 4.729	0.967, 138.186
	5%, 95%	14.303, 5334.180	172.571, 5294.820	172.571, 5294.820	1.057, 32.968	0.980, 4.724	1.057, 11.448
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.046, 2.046	2.046, 2.046
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.046	2.046
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.046, 2.046	2.046, 2.046
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1672.420, 877.450	1672.420, 877.450	1.255, 1.255	NA, NA	1.255, 1.255
	SD, SE	NA, NA	2152.4900, 1242.7400	2152.4900, 1242.7400	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	590.320	590.320	1.255	NA	1.255
	MIN, MAX	NA, NA	275.677, 4151.250	275.677, 4151.250	1.255, 1.255	NA, NA	1.255, 1.255
	5%, 95%	NA, NA	275.677, 4151.250	275.677, 4151.250	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 5 of 7)

Lab: Harrogate
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17035.500, 17035.500	17035.500, 17035.500	18.495, 18.495	6.689, 5.887	10.624, 8.623
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.4901, 3.1750	7.5194, 4.3413
	MEDIAN	NA	17035.500	17035.500	18.495	6.689	9.864
	MIN, MAX	NA, NA	17035.523, 17035.523	17035.523, 17035.523	18.495, 18.495	3.514, 9.864	3.514, 18.495
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.514, 9.864	3.514, 18.495
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	14416.000, 9951.700	15239.700, 9770.930	14917.400, 9841.270	55.236, 18.053	14.904, 12.900	33.417, 15.052
	SD, SE	8703.3800, 2051.4100	12375.2000, 2338.7000	10984.9000, 1619.6400	121.7380, 23.0063	9.3688, 1.6309	84.4189, 10.8087
	MEDIAN	14301.700	11588.600	12528.700	12.438	12.207	12.299
	MIN, MAX	136.475, 30169.969	717.144, 39072.999	136.475, 39072.999	3.267, 543.506	4.932, 47.939	3.267, 543.506
	5%, 95%	136.475, 30170.000	939.306, 37492.900	939.306, 35943.600	4.007, 388.728	5.918, 42.076	5.857, 106.334
	BLQ Values Included	0	0	0	13	26	39
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8.446, 8.446	8.446, 8.446
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8.446	8.446
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8.446, 8.446	8.446, 8.446
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	10979.200, 5962.650	10979.200, 5962.650	4.994, 4.994	NA, NA	4.994, 4.994
	SD, SE	NA, NA	13339.3000, 7701.4500	13339.3000, 7701.4500	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5110.460	5110.460	4.994	NA	4.994
	MIN, MAX	NA, NA	1580.459, 26246.655	1580.459, 26246.655	4.994, 4.994	NA, NA	4.994, 4.994
	5%, 95%	NA, NA	1580.460, 26246.700	1580.460, 26246.700	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 6 of 7)

Lab: Harrogate
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	19731.900, 19731.900	19731.900, 19731.900	16.954, 16.954	5.857, 5.577	9.556, 8.079
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.5286, 1.7880	6.6517, 3.8403
	MEDIAN	NA	19731.900	19731.900	16.954	5.857	7.645
	MIN, MAX	NA, NA	19731.859, 19731.859	19731.859, 19731.859	16.954, 16.954	4.069, 7.645	4.069, 16.954
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	4.069, 7.645	4.069, 16.954
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	14569.100, 10144.000	16096.300, 11393.400	15485.400, 10876.100	95.443, 16.203	15.394, 13.433	52.138, 14.541
	SD, SE	7907.3400, 1863.7800	12827.3000, 2468.6200	11043.5000, 1646.2600	402.8890, 76.1389	8.7595, 1.5248	273.3180, 34.9947
	MEDIAN	13302.600	12833.600	12940.600	10.357	13.563	13.255
	MIN, MAX	66.027, 28411.649	1188.489, 58890.910	66.027, 58890.910	3.853, 2148.842	4.624, 43.944	3.853, 2148.842
	5%, 95%	66.027, 28411.600	1432.250, 35822.800	1432.250, 33416.500	5.024, 92.019	5.641, 37.976	5.055, 43.944
	BLQ Values Included	0	0	0	17	30	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	14.426, 14.426	14.426, 14.426
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	14.426	14.426
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	14.426, 14.426	14.426, 14.426
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	13554.200, 4588.720	13554.200, 4588.720	9.402, 9.402	NA, NA	9.402, 9.402
	SD, SE	NA, NA	20254.0000, 11693.7000	20254.0000, 11693.7000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2817.680	2817.680	9.402	NA	9.402
	MIN, MAX	NA, NA	928.893, 36916.112	928.893, 36916.112	9.402, 9.402	NA, NA	9.402, 9.402
	5%, 95%	NA, NA	928.893, 36916.100	928.893, 36916.100	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 7 of ?)

Lab: Harrogate
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	30136.000, 30136.000	30136.000, 30136.000	17.940, 17.940	9.611, 9.122	12.387, 11.429
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.2808, 3.0270	5.6821, 3.2806
	MEDIAN	NA	30136.000	30136.000	17.940	9.611	12.638
	MIN, MAX	NA, NA	30135.975, 30135.975	30135.975, 30135.975	17.940, 17.940	6.584, 12.638	6.584, 17.940
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.584, 12.638	6.584, 17.940
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	17482.900, 9116.140	17190.800, 13838.800	17309.100, 11687.500	21.752, 15.424	13.806, 12.836	17.453, 13.965
	SD, SE	15968.9000, 3873.0400	9259.2400, 1851.8500	12236.1000, 1888.0700	23.9596, 4.5279	5.3559, 0.9323	17.0168, 2.1788
	MEDIAN	11413.100	15217.800	14667.700	13.101	12.638	12.947
	MIN, MAX	62.026, 47682.083	587.105, 35443.633	62.026, 47682.083	4.624, 121.820	5.795, 29.222	4.624, 121.820
	5%, 95%	62.026, 47682.100	5161.340, 33957.000	1780.260, 45094.600	4.624, 51.848	6.103, 24.339	6.103, 44.536
	BLQ Values Included	0	0	0	17	31	48
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	14.975, 14.975	14.975, 14.975
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	14.975	14.975
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	14.975, 14.975	14.975, 14.975
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6397.890, 4723.650	6397.890, 4723.650	8.816, 8.816	NA, NA	8.816, 8.816
	SD, SE	NA, NA	6253.0200, 3610.1800	6253.0200, 3610.1800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2989.830	2989.830	8.816	NA	8.816
	MIN, MAX	NA, NA	2589.300, 13614.552	2589.300, 13614.552	8.816, 8.816	NA, NA	8.816, 8.816
	5%, 95%	NA, NA	2589.300, 13614.600	2589.300, 13614.600	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	22301.100, 22301.100	22301.100, 22301.100	17.796, 17.796	7.386, 7.357	10.856, 9.876
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.9129, 0.6455	6.0451, 3.4901
	MEDIAN	NA	22301.100	22301.100	17.796	7.386	8.031
	MIN, MAX	NA, NA	22301.100, 22301.100	22301.100, 22301.100	17.796, 17.796	6.740, 8.031	6.740, 17.796
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.740, 8.031	6.740, 17.796
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	15538.800, 10412.600	15605.600, 11368.000	15579.500, 10984.100	57.477, 19.128	14.701, 13.384	34.336, 15.768
	SD, SE	9466.5800, 2231.2900	10758.0000, 2033.0800	10163.5000, 1498.5300	160.7330, 30.3756	6.4417, 1.1214	110.0450, 14.0898
	MEDIAN	14828.400	11925.500	12614.200	12.042	13.707	13.522
	MIN, MAX	88.176, 32885.200	1001.810, 42596.000	88.176, 42596.000	6.021, 851.919	5.960, 29.152	5.960, 851.919
	5%, 95%	88.176, 32885.200	1063.900, 32642.600	1063.900, 32642.600	6.514, 203.248	6.042, 29.125	6.514, 70.579
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	12.616, 12.616	12.616, 12.616
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	12.616	12.616
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	12.616, 12.616	12.616, 12.616
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	10310.400, 5409.470	10310.400, 5409.470	7.737, 7.737	NA, NA	7.737, 7.737
	SD, SE	NA, NA	13270.1000, 7661.4800	13270.1000, 7661.4800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3639.320	3639.320	7.737	NA	7.737
	MIN, MAX	NA, NA	1699.550, 25592.400	1699.550, 25592.400	7.737, 7.737	NA, NA	7.737, 7.737
	5%, 95%	NA, NA	1699.550, 25592.400	1699.550, 25592.400	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.889, 1.889	1.889, 1.889	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.889	1.889	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.889, 1.889	1.889, 1.889	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1.996, 1.221	2.138, 1.426	2.082, 1.342	0.005, NA	0.002, 0.002	0.004, NA
	SD, SE	2.0759, 0.4893	1.5956, 0.3015	1.7777, 0.2621	0.0112, 0.0021	0.0018, 0.0003	0.0078, 0.0010
	MEDIAN	1.526	1.792	1.727	0.001	0.002	0.002
	MIN, MAX	0.021, 9.353	0.097, 5.798	0.021, 9.353	0.000, 0.044	0.001, 0.011	0.000, 0.044
	5%, 95%	0.021, 9.353	0.100, 5.254	0.100, 5.254	0.000, 0.042	0.001, 0.005	0.001, 0.011
	BLQ Values Included	0	0	0	13	26	39
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.002	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.116, 0.683	1.116, 0.683	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	1.2789, 0.7384	1.2789, 0.7384	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.534	0.534	0.001	NA	0.001
	MIN, MAX	NA, NA	0.231, 2.582	0.231, 2.582	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.231, 2.582	0.231, 2.582	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.190, 2.190	2.190, 2.190	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	2.190	2.190	0.001	0.001	0.001
	MIN, MAX	NA, NA	2.190, 2.190	2.190, 2.190	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1.880, 1.210	2.070, 1.457	1.994, 1.352	0.014, NA	0.002, 0.002	0.008, NA
	SD, SE	1.6531, 0.3896	1.7326, 0.3334	1.6848, 0.2512	0.0626, 0.0118	0.0014, 0.0002	0.0424, 0.0054
	MEDIAN	1.681	1.752	1.686	0.001	0.002	0.002
	MIN, MAX	0.012, 7.451	0.144, 7.495	0.012, 7.495	0.000, 0.333	0.001, 0.007	0.000, 0.333
	5%, 95%	0.012, 7.451	0.182, 6.431	0.182, 6.431	0.000, 0.017	0.001, 0.004	0.001, 0.004
	BLQ Values Included	0	0	0	17	30	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.607, 0.663	1.607, 0.663	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	2.2135, 1.2780	2.2135, 1.2780	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.539	0.539	0.001	NA	0.001
	MIN, MAX	NA, NA	0.130, 4.152	0.130, 4.152	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.130, 4.152	0.130, 4.152	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.943, 2.943	2.943, 2.943	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	2.943	2.943	0.001	0.001	0.001
	MIN, MAX	NA, NA	2.943, 2.943	2.943, 2.943	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1.814, 1.068	2.318, 1.848	2.114, 1.480	0.002, NA	0.002, 0.002	0.002, NA
	SD, SE	1.3903, 0.3372	1.3634, 0.2727	1.3802, 0.2130	0.0022, 0.0004	0.0012, 0.0002	0.0017, 0.0002
	MEDIAN	1.555	2.175	2.056	0.001	0.002	0.002
	MIN, MAX	0.009, 4.966	0.095, 5.794	0.009, 5.794	0.000, 0.011	0.001, 0.005	0.000, 0.011
	5%, 95%	0.009, 4.966	0.558, 5.392	0.200, 4.966	0.000, 0.005	0.001, 0.005	0.000, 0.005
	BLQ Values Included	0	0	0	17	31	48
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.621, 0.985	1.621, 0.985	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	1.9483, 1.1248	1.9483, 1.1248	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.499	0.499	0.002	NA	0.002
	MIN, MAX	NA, NA	0.494, 3.871	0.494, 3.871	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	0.494, 3.871	0.494, 3.871	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 12 of ?)

Lab: Harrogate
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.341, 2.341	2.341, 2.341	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	2.341	2.341	0.001	0.001	0.001
	MIN, MAX	NA, NA	2.341, 2.341	2.341, 2.341	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1.899, 1.237	2.160, 1.574	2.058, 1.433	0.007, NA	0.002, 0.002	0.004, NA
	SD, SE	1.4598, 0.3441	1.4976, 0.2830	1.4722, 0.2171	0.0235, 0.0044	0.0012, 0.0002	0.0160, 0.0020
	MEDIAN	1.741	1.849	1.811	0.002	0.002	0.002
	MIN, MAX	0.014, 6.341	0.122, 5.778	0.014, 6.341	0.000, 0.126	0.001, 0.006	0.000, 0.126
	5%, 95%	0.014, 6.341	0.156, 5.620	0.156, 5.620	0.000, 0.015	0.001, 0.004	0.001, 0.008
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.448, 0.808	1.448, 0.808	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	1.8113, 1.0458	1.8113, 1.0458	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.524	0.524	0.001	NA	0.001
	MIN, MAX	NA, NA	0.285, 3.535	0.285, 3.535	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.285, 3.535	0.285, 3.535	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 13 of ?)

Lab: Harrogate
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11.646, 11.646	11.646, 11.646	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	11.646	11.646	0.006	0.003	0.006
	MIN, MAX	NA, NA	11.646, 11.646	11.646, 11.646	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	12.307, 7.529	13.179, 8.793	12.837, 8.275	0.032, NA	0.014, 0.011	0.022, NA
	SD, SE	12.7977, 3.0165	9.8367, 1.8590	10.9597, 1.6159	0.0691, 0.0130	0.0111, 0.0019	0.0480, 0.0061
	MEDIAN	9.408	11.045	10.644	0.006	0.012	0.012
	MIN, MAX	0.129, 57.661	0.598, 35.745	0.129, 57.661	0.000, 0.271	0.006, 0.068	0.000, 0.271
	5%, 95%	0.129, 57.661	0.617, 32.391	0.617, 32.391	0.000, 0.259	0.006, 0.031	0.006, 0.068
	BLQ Values Included	0	0	0	13	26	39
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.012, 0.012	0.012, 0.012
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.012	0.012
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.012, 0.012	0.012, 0.012
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6.878, 4.210	6.878, 4.210	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	7.8844, 4.5521	7.8844, 4.5521	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.292	3.292	0.006	NA	0.006
	MIN, MAX	NA, NA	1.424, 15.918	1.424, 15.918	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	1.424, 15.918	1.424, 15.918	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13.501, 13.501	13.501, 13.501	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	13.501	13.501	0.006	0.003	0.006
	MIN, MAX	NA, NA	13.501, 13.501	13.501, 13.501	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	11.587, 7.457	12.761, 8.981	12.292, 8.337	0.087, NA	0.013, 0.011	0.047, NA
	SD, SE	10.1915, 2.4022	10.6816, 2.0557	10.3870, 1.5484	0.3859, 0.0729	0.0087, 0.0015	0.2615, 0.0335
	MEDIAN	10.361	10.801	10.394	0.006	0.012	0.012
	MIN, MAX	0.074, 45.935	0.888, 46.207	0.074, 46.207	0.000, 2.053	0.006, 0.043	0.000, 2.053
	5%, 95%	0.074, 45.935	1.122, 39.647	1.122, 39.647	0.000, 0.105	0.006, 0.025	0.006, 0.025
	BLQ Values Included	0	0	0	17	30	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.018	0.018, 0.018
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.018	0.018
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.018	0.018, 0.018
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	9.907, 4.084	9.907, 4.084	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	13.6463, 7.8787	13.6463, 7.8787	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.323	3.323	0.006	NA	0.006
	MIN, MAX	NA, NA	0.801, 25.597	0.801, 25.597	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	0.801, 25.597	0.801, 25.597	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	18.144, 18.144	18.144, 18.144	0.006, 0.006	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	18.144	18.144	0.006	0.006	0.006
	MIN, MAX	NA, NA	18.144, 18.144	18.144, 18.144	0.006, 0.006	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	11.184, 6.582	14.289, 11.395	13.032, 9.125	0.011, NA	0.013, 0.011	0.012, NA
	SD, SE	8.5709, 2.0788	8.4051, 1.6810	8.5088, 1.3129	0.0135, 0.0025	0.0074, 0.0013	0.0106, 0.0014
	MEDIAN	9.587	13.409	12.673	0.006	0.012	0.012
	MIN, MAX	0.055, 30.615	0.586, 35.720	0.055, 35.720	0.000, 0.068	0.006, 0.031	0.000, 0.068
	5%, 95%	0.055, 30.615	3.440, 33.242	1.233, 30.615	0.000, 0.031	0.006, 0.031	0.000, 0.031
	BLQ Values Included	0	0	0	17	31	48
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.018	0.018, 0.018
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.018	0.018
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.018	0.018, 0.018
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	9.996, 6.070	9.996, 6.070	0.012, 0.012	NA, NA	0.012, 0.012
	SD, SE	NA, NA	12.0112, 6.9347	12.0112, 6.9347	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.076	3.076	0.012	NA	0.012
	MIN, MAX	NA, NA	3.046, 23.865	3.046, 23.865	0.012, 0.012	NA, NA	0.012, 0.012
	5%, 95%	NA, NA	3.046, 23.865	3.046, 23.865	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	14.430, 14.430	14.430, 14.430	0.006, 0.006	0.004, 0.003	0.005, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0028, 0.0020	0.0023, 0.0013
	MEDIAN	NA	14.430	14.430	0.006	0.004	0.006
	MIN, MAX	NA, NA	14.430, 14.430	14.430, 14.430	0.006, 0.006	0.002, 0.006	0.002, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.006	0.002, 0.006
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	11.710, 7.628	13.315, 9.703	12.687, 8.831	0.043, 0.011	0.013, 0.012	0.027, 0.011
	SD, SE	8.9997, 2.1212	9.2329, 1.7449	9.0760, 1.3382	0.1456, 0.0275	0.0073, 0.0013	0.0990, 0.0127
	MEDIAN	10.731	11.396	11.165	0.009	0.012	0.010
	MIN, MAX	0.086, 39.094	0.753, 35.623	0.086, 39.094	0.002, 0.779	0.006, 0.037	0.002, 0.779
	5%, 95%	0.086, 39.094	0.960, 34.649	0.960, 34.649	0.002, 0.094	0.006, 0.025	0.004, 0.049
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.016, 0.016	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.016	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.016, 0.016	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	8.927, 4.982	8.927, 4.982	0.008, 0.008	NA, NA	0.008, 0.008
	SD, SE	NA, NA	11.1669, 6.4472	11.1669, 6.4472	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.230	3.230	0.008	NA	0.008
	MIN, MAX	NA, NA	1.757, 21.793	1.757, 21.793	0.008, 0.008	NA, NA	0.008, 0.008
	5%, 95%	NA, NA	1.757, 21.793	1.757, 21.793	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2527.230, 2527.230	2527.230, 2527.230	3.000, 3.000	1.085, 0.955	1.723, 1.399
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.7283, 0.5150	1.2197, 0.7042
	MEDIAN	NA	2527.230	2527.230	3.000	1.085	1.600
	MIN, MAX	NA, NA	2527.232, 2527.232	2527.232, 2527.232	3.000, 3.000	0.570, 1.600	0.570, 3.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.570, 1.600	0.570, 3.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1685.190, 1137.840	1820.790, 1038.130	1767.730, 1076.060	8.293, 2.537	2.271, 1.978	5.035, 2.217
	SD, SE	1101.8200, 259.7020	1666.1600, 314.8740	1459.0300, 215.1220	19.9975, 3.7792	1.5568, 0.2710	13.7986, 1.7667
	MEDIAN	1444.190	1281.880	1417.230	1.619	1.950	1.862
	MIN, MAX	18.048, 3521.714	76.527, 5245.860	18.048, 5245.860	0.530, 93.100	0.800, 9.792	0.530, 93.100
	5%, 95%	18.048, 3521.710	83.814, 5088.650	83.814, 4727.380	0.780, 58.311	0.960, 3.350	0.950, 13.992
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.370, 1.370	1.370, 1.370
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.370	1.370
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.370, 1.370	1.370, 1.370
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1136.380, 740.201	1136.380, 740.201	0.810, 0.810	NA, NA	0.810, 0.810
	SD, SE	NA, NA	1159.0800, 669.1970	1159.0800, 669.1970	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	746.216	746.216	0.810	NA	0.810
	MIN, MAX	NA, NA	222.720, 2440.200	222.720, 2440.200	0.810, 0.810	NA, NA	0.810, 0.810
	5%, 95%	NA, NA	222.720, 2440.200	222.720, 2440.200	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2122.410, 2122.410	2122.410, 2122.410	2.750, 2.750	0.950, 0.905	1.550, 1.310
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4101, 0.2900	1.0789, 0.6229
	MEDIAN	NA	2122.410	2122.410	2.750	0.950	1.240
	MIN, MAX	NA, NA	2122.406, 2122.406	2122.406, 2122.406	2.750, 2.750	0.660, 1.240	0.660, 2.750
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.660, 1.240	0.660, 2.750
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1746.580, 1234.840	1895.520, 1203.900	1835.950, 1216.180	13.339, 2.354	2.411, 2.124	7.427, 2.227
	SD, SE	992.7280, 233.9880	1575.1200, 303.1330	1360.9800, 202.8830	56.7564, 10.7260	1.4081, 0.2451	38.4810, 4.9270
	MEDIAN	1592.530	1490.080	1573.750	1.680	2.200	2.150
	MIN, MAX	10.980, 3494.785	81.312, 5904.527	10.980, 5904.527	0.625, 302.670	0.750, 8.514	0.625, 302.670
	5%, 95%	10.980, 3494.790	94.792, 4764.320	94.792, 4729.200	0.815, 12.512	0.915, 4.585	0.820, 6.758
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.950, 1.950	1.950, 1.950
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.950	1.950
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.950, 1.950	1.950, 1.950
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1253.180, 538.244	1253.180, 538.244	1.525, 1.525	NA, NA	1.525, 1.525
	SD, SE	NA, NA	1728.8200, 998.1350	1728.8200, 998.1350	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	394.383	394.383	1.525	NA	1.525
	MIN, MAX	NA, NA	121.910, 3243.240	121.910, 3243.240	1.525, 1.525	NA, NA	1.525, 1.525
	5%, 95%	NA, NA	121.910, 3243.240	121.910, 3243.240	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537598

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3806.090, 3806.090	3806.090, 3806.090	2.910, 2.910	1.559, 1.480	2.009, 1.854
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.6944, 0.4910	0.9217, 0.5321
	MEDIAN	NA	3806.090	3806.090	2.910	1.559	2.050
	MIN, MAX	NA, NA	3806.085, 3806.085	3806.085, 3806.085	2.910, 2.910	1.068, 2.050	1.068, 2.910
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.068, 2.050	1.068, 2.910
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	2172.220, 1008.700	2026.020, 1538.000	2085.200, 1296.600	2.740, 2.120	2.186, 2.040	2.440, 2.076
	SD, SE	2176.7000, 527.9280	1189.8900, 237.9780	1638.0000, 252.7490	2.6284, 0.4967	0.8250, 0.1436	1.8840, 0.2412
	MEDIAN	1269.580	2060.820	1746.430	1.900	2.050	2.030
	MIN, MAX	5.450, 6614.080	55.800, 4262.175	5.450, 6614.080	0.750, 13.650	0.940, 4.740	0.750, 13.650
	5%, 95%	5.450, 6614.080	438.490, 4138.430	161.699, 5668.540	0.750, 7.259	0.990, 3.350	0.990, 4.740
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.735, 1.735	1.735, 1.735
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.735	1.735
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.735, 1.735	1.735, 1.735
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	718.859, 616.547	718.859, 616.547	1.430, 1.430	NA, NA	1.430, 1.430
	SD, SE	NA, NA	512.6830, 295.9970	512.6830, 295.9970	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	428.560	428.560	1.430	NA	1.430
	MIN, MAX	NA, NA	417.200, 1310.818	417.200, 1310.818	1.430, 1.430	NA, NA	1.430, 1.430
	5%, 95%	NA, NA	417.200, 1310.820	417.200, 1310.820	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2818.570, 2818.570	2818.570, 2818.570	2.887, 2.887	1.198, 1.193	1.761, 1.602
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.1485, 0.1050	0.9808, 0.5663
	MEDIAN	NA	2818.570	2818.570	2.887	1.198	1.303
	MIN, MAX	NA, NA	2818.570, 2818.570	2818.570, 2818.570	2.887, 2.887	1.093, 1.303	1.093, 2.887
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.093, 1.303	1.093, 2.887
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1878.760, 1253.990	1844.800, 1251.150	1858.090, 1252.260	8.124, 2.733	2.289, 2.099	4.968, 2.369
	SD, SE	1166.6200, 274.9750	1379.8700, 260.7700	1287.1900, 189.7860	23.0327, 4.3528	0.9803, 0.1706	15.7428, 2.0157
	MEDIAN	1786.220	1574.520	1696.910	1.863	2.223	2.150
	MIN, MAX	11.493, 3792.220	85.660, 4824.560	11.493, 4824.560	0.793, 121.310	0.967, 5.163	0.793, 121.310
	5%, 95%	11.493, 3792.220	130.092, 4300.000	130.092, 4297.930	0.865, 33.074	0.980, 4.270	0.980, 8.342
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.685, 1.685	1.685, 1.685
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.685	1.685
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.685, 1.685	1.685, 1.685
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1036.140, 676.551	1036.140, 676.551	1.255, 1.255	NA, NA	1.255, 1.255
	SD, SE	NA, NA	1129.7900, 652.2830	1129.7900, 652.2830	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	523.053	523.053	1.255	NA	1.255
	MIN, MAX	NA, NA	253.943, 2331.420	253.943, 2331.420	1.255, 1.255	NA, NA	1.255, 1.255
	5%, 95%	NA, NA	253.943, 2331.420	253.943, 2331.420	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537600

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	15580.400, 15580.400	15580.400, 15580.400	18.495, 18.495	6.689, 5.887	10.624, 8.623
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.4901, 3.1750	7.5194, 4.3413
	MEDIAN	NA	15580.400	15580.400	18.495	6.689	9.864
	MIN, MAX	NA, NA	15580.385, 15580.385	15580.385, 15580.385	18.495, 18.495	3.514, 9.864	3.514, 18.495
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.514, 9.864	3.514, 18.495
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	10389.200, 7014.800	11225.200, 6400.040	10898.000, 6633.910	51.126, 15.638	14.001, 12.193	31.042, 13.669
	SD, SE	6792.7300, 1601.0600	10271.9000, 1941.2000	8994.8900, 1326.2200	123.2840, 23.2986	9.5980, 1.6708	85.0685, 10.8919
	MEDIAN	8903.460	7902.810	8737.190	9.978	12.022	11.479
	MIN, MAX	111.266, 21711.367	471.789, 32340.727	111.266, 32340.727	3.267, 573.962	4.932, 60.368	3.267, 573.962
	5%, 95%	111.266, 21711.400	516.713, 31371.500	516.713, 29144.300	4.809, 359.487	5.918, 20.653	5.857, 86.261
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8.446, 8.446	8.446, 8.446
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8.446	8.446
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8.446, 8.446	8.446, 8.446
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	7005.770, 4563.340	7005.770, 4563.340	4.994, 4.994	NA, NA	4.994, 4.994
	SD, SE	NA, NA	7145.7500, 4125.6000	7145.7500, 4125.6000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4600.420	4600.420	4.994	NA	4.994
	MIN, MAX	NA, NA	1373.069, 15043.833	1373.069, 15043.833	4.994, 4.994	NA, NA	4.994, 4.994
	5%, 95%	NA, NA	1373.070, 15043.800	1373.070, 15043.800	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537601

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13084.600, 13084.600	13084.600, 13084.600	16.954, 16.954	5.857, 5.577	9.556, 8.079
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.5286, 1.7880	6.6517, 3.8403
	MEDIAN	NA	13084.600	13084.600	16.954	5.857	7.645
	MIN, MAX	NA, NA	13084.633, 13084.633	13084.633, 13084.633	16.954, 16.954	4.069, 7.645	4.069, 16.954
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	4.069, 7.645	4.069, 16.954
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	10767.600, 7612.790	11685.900, 7422.060	11318.600, 7497.770	82.235, 14.512	14.863, 13.094	45.788, 13.727
	SD, SE	6120.1700, 1442.5400	9710.6400, 1868.8100	8390.4400, 1250.7700	349.9030, 66.1255	8.6807, 1.5111	237.2360, 30.3749
	MEDIAN	9817.950	9186.320	9702.170	10.357	13.563	13.255
	MIN, MAX	67.692, 21545.350	501.288, 36401.409	67.692, 36401.409	3.853, 1865.961	4.624, 52.489	3.853, 1865.961
	5%, 95%	67.692, 21545.400	584.393, 29372.000	584.393, 29155.500	5.024, 77.136	5.641, 28.267	5.055, 41.663
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	12.022, 12.022	12.022, 12.022
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	12.022	12.022
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	12.022, 12.022	12.022, 12.022
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	7725.840, 3318.270	7725.840, 3318.270	9.402, 9.402	NA, NA	9.402, 9.402
	SD, SE	NA, NA	10658.2000, 6153.5000	10658.2000, 6153.5000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2431.370	2431.370	9.402	NA	9.402
	MIN, MAX	NA, NA	751.575, 19994.575	751.575, 19994.575	9.402, 9.402	NA, NA	9.402, 9.402
	5%, 95%	NA, NA	751.575, 19994.600	751.575, 19994.600	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	23464.500, 23464.500	23464.500, 23464.500	17.940, 17.940	9.611, 9.122	12.387, 11.429
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.2808, 3.0270	5.6821, 3.2806
	MEDIAN	NA	23464.500	23464.500	17.940	9.611	12.638
	MIN, MAX	NA, NA	23464.514, 23464.514	23464.514, 23464.514	17.940, 17.940	6.584, 12.638	6.584, 17.940
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.584, 12.638	6.584, 17.940
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	13391.800, 6218.640	12490.400, 9481.790	12855.200, 7993.550	16.894, 13.069	13.477, 12.579	15.045, 12.802
	SD, SE	13419.4000, 3254.6800	7335.6700, 1467.1300	10098.3000, 1558.2000	16.2042, 3.0623	5.0858, 0.8853	11.6147, 1.4871
	MEDIAN	7826.960	12705.000	10766.700	11.714	12.638	12.515
	MIN, MAX	33.599, 40775.803	344.007, 26276.309	33.599, 40775.803	4.624, 84.152	5.795, 29.222	4.624, 84.152
	5%, 95%	33.599, 40775.800	2703.290, 25513.400	996.874, 34946.500	4.624, 44.752	6.103, 20.653	6.103, 29.222
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10.696, 10.696	10.696, 10.696
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10.696	10.696
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10.696, 10.696	10.696, 10.696
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4431.770, 3801.010	4431.770, 3801.010	8.816, 8.816	NA, NA	8.816, 8.816
	SD, SE	NA, NA	3160.6900, 1824.8200	3160.6900, 1824.8200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2642.070	2642.070	8.816	NA	8.816
	MIN, MAX	NA, NA	2572.038, 8081.193	2572.038, 8081.193	8.816, 8.816	NA, NA	8.816, 8.816
	5%, 95%	NA, NA	2572.040, 8081.190	2572.040, 8081.190	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17376.500, 17376.500	17376.500, 17376.500	17.796, 17.796	7.386, 7.357	10.856, 9.876
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.9129, 0.6455	6.0451, 3.4901
	MEDIAN	NA	17376.500	17376.500	17.796	7.386	8.031
	MIN, MAX	NA, NA	17376.500, 17376.500	17376.500, 17376.500	17.796, 17.796	6.740, 8.031	6.740, 17.796
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.740, 8.031	6.740, 17.796
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	11582.500, 7730.810	11373.200, 7713.350	11455.100, 7720.180	50.085, 16.847	14.114, 12.938	30.625, 14.605
	SD, SE	7192.2100, 1695.2200	8506.8800, 1607.6500	7935.5300, 1170.0300	141.9970, 26.8350	6.0435, 1.0520	97.0546, 12.4266
	MEDIAN	11012.100	9706.920	10461.500	11.484	13.707	13.255
	MIN, MAX	70.852, 23379.000	528.091, 29743.400	70.852, 29743.400	4.891, 747.878	5.960, 31.832	4.891, 747.878
	5%, 95%	70.852, 23379.000	802.015, 26509.500	802.015, 26496.800	5.331, 203.904	6.042, 26.323	6.042, 51.426
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10.388, 10.388	10.388, 10.388
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10.388	10.388
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10.388, 10.388	10.388, 10.388
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6387.790, 4170.940	6387.790, 4170.940	7.737, 7.737	NA, NA	7.737, 7.737
	SD, SE	NA, NA	6965.1400, 4021.3200	6965.1400, 4021.3200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3224.620	3224.620	7.737	NA	7.737
	MIN, MAX	NA, NA	1565.560, 14373.200	1565.560, 14373.200	7.737, 7.737	NA, NA	7.737, 7.737
	5%, 95%	NA, NA	1565.560, 14373.200	1565.560, 14373.200	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.727, 1.727	1.727, 1.727	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.727	1.727	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.727, 1.727	1.727, 1.727	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1.564, 0.861	1.625, 0.934	1.601, 0.905	0.005, NA	0.002, 0.002	0.003, NA
	SD, SE	1.9898, 0.4690	1.4811, 0.2799	1.6771, 0.2473	0.0109, 0.0021	0.0022, 0.0004	0.0076, 0.0010
	MEDIAN	1.038	1.072	1.072	0.001	0.002	0.002
	MIN, MAX	0.017, 8.892	0.050, 5.613	0.017, 8.892	0.000, 0.044	0.001, 0.014	0.000, 0.044
	5%, 95%	0.017, 8.892	0.071, 5.001	0.071, 5.001	0.000, 0.041	0.001, 0.003	0.001, 0.012
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.002	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	0.721, 0.523	0.721, 0.523	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	0.6723, 0.3882	0.6723, 0.3882	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.481	0.481	0.001	NA	0.001
	MIN, MAX	NA, NA	0.201, 1.480	0.201, 1.480	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.201, 1.480	0.201, 1.480	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.452, 1.452	1.452, 1.452	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.452	1.452	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.452, 1.452	1.452, 1.452	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1.463, 0.906	1.515, 0.949	1.494, 0.932	0.012, NA	0.002, 0.002	0.007, NA
	SD, SE	1.5262, 0.3597	1.3601, 0.2617	1.4120, 0.2105	0.0543, 0.0103	0.0014, 0.0003	0.0368, 0.0047
	MEDIAN	1.135	1.262	1.262	0.001	0.002	0.002
	MIN, MAX	0.012, 6.916	0.064, 5.630	0.012, 6.916	0.000, 0.289	0.001, 0.008	0.000, 0.289
	5%, 95%	0.012, 6.916	0.071, 4.633	0.071, 4.633	0.000, 0.014	0.001, 0.004	0.001, 0.004
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	0.940, 0.479	0.940, 0.479	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	1.1481, 0.6629	1.1481, 0.6629	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.465	0.465	0.001	NA	0.001
	MIN, MAX	NA, NA	0.105, 2.249	0.105, 2.249	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.105, 2.249	0.105, 2.249	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.292, 2.292	2.292, 2.292	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	2.292	2.292	0.001	0.001	0.001
	MIN, MAX	NA, NA	2.292, 2.292	2.292, 2.292	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1.392, 0.730	1.713, 1.267	1.583, 1.013	0.001, NA	0.002, 0.002	0.002, NA
	SD, SE	1.1591, 0.2811	1.1993, 0.2399	1.1797, 0.1820	0.0015, 0.0003	0.0011, 0.0002	0.0013, 0.0002
	MEDIAN	1.218	1.493	1.471	0.001	0.002	0.002
	MIN, MAX	0.005, 4.246	0.056, 5.060	0.005, 5.060	0.000, 0.008	0.001, 0.005	0.000, 0.008
	5%, 95%	0.005, 4.246	0.357, 4.177	0.107, 4.177	0.000, 0.003	0.001, 0.005	0.000, 0.004
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.002	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.077, 0.792	1.077, 0.792	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	1.0580, 0.6108	1.0580, 0.6108	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.491	0.491	0.002	NA	0.002
	MIN, MAX	NA, NA	0.441, 2.298	0.441, 2.298	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	0.441, 2.298	0.441, 2.298	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.824, 1.824	1.824, 1.824	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.824	1.824	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.824, 1.824	1.824, 1.824	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1.477, 0.920	1.605, 1.067	1.555, 1.007	0.006, NA	0.002, 0.002	0.004, NA
	SD, SE	1.3164, 0.3103	1.2924, 0.2442	1.2887, 0.1900	0.0207, 0.0039	0.0013, 0.0002	0.0141, 0.0018
	MEDIAN	1.237	1.362	1.351	0.001	0.002	0.002
	MIN, MAX	0.011, 5.866	0.061, 5.434	0.011, 5.866	0.000, 0.111	0.001, 0.007	0.000, 0.111
	5%, 95%	0.011, 5.866	0.119, 4.066	0.119, 4.066	0.000, 0.015	0.001, 0.004	0.001, 0.006
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.002	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.002	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	0.912, 0.627	0.912, 0.627	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	0.9548, 0.5512	0.9548, 0.5512	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.462	0.462	0.001	NA	0.001
	MIN, MAX	NA, NA	0.266, 2.009	0.266, 2.009	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.266, 2.009	0.266, 2.009	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537608

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.647, 10.647	10.647, 10.647	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	10.647	10.647	0.006	0.003	0.006
	MIN, MAX	NA, NA	10.647, 10.647	10.647, 10.647	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	9.640, 5.307	10.016, 5.757	9.869, 5.576	0.030, NA	0.013, 0.011	0.021, NA
	SD, SE	12.2671, 2.8914	9.1308, 1.7256	10.3395, 1.5245	0.0675, 0.0128	0.0137, 0.0024	0.0472, 0.0060
	MEDIAN	6.396	6.606	6.606	0.006	0.012	0.012
	MIN, MAX	0.105, 54.819	0.308, 34.604	0.105, 54.819	0.000, 0.271	0.006, 0.086	0.000, 0.271
	5%, 95%	0.105, 54.819	0.438, 30.831	0.438, 30.831	0.000, 0.253	0.006, 0.018	0.006, 0.074
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.012, 0.012	0.012, 0.012
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.012	0.012
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.012, 0.012	0.012, 0.012
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.443, 3.224	4.443, 3.224	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	4.1450, 2.3931	4.1450, 2.3931	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.965	2.965	0.006	NA	0.006
	MIN, MAX	NA, NA	1.239, 9.124	1.239, 9.124	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	1.239, 9.124	1.239, 9.124	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537609

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	8.952, 8.952	8.952, 8.952	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	8.952	8.952	0.006	0.003	0.006
	MIN, MAX	NA, NA	8.952, 8.952	8.952, 8.952	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	9.017, 5.588	9.343, 5.852	9.212, 5.745	0.075, NA	0.013, 0.011	0.041, NA
	SD, SE	9.4091, 2.2178	8.3848, 1.6137	8.7049, 1.2977	0.3349, 0.0633	0.0089, 0.0016	0.2269, 0.0291
	MEDIAN	6.994	7.780	7.780	0.006	0.012	0.012
	MIN, MAX	0.074, 42.637	0.395, 34.709	0.074, 42.637	0.000, 1.782	0.006, 0.049	0.000, 1.782
	5%, 95%	0.074, 42.637	0.438, 28.562	0.438, 28.562	0.000, 0.086	0.006, 0.025	0.006, 0.025
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.018	0.018, 0.018
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.018	0.018
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.018	0.018, 0.018
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5.793, 2.952	5.793, 2.952	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	7.0781, 4.0866	7.0781, 4.0866	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.867	2.867	0.006	NA	0.006
	MIN, MAX	NA, NA	0.647, 13.865	0.647, 13.865	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	0.647, 13.865	0.647, 13.865	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	14.130, 14.130	14.130, 14.130	0.006, 0.006	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	14.130	14.130	0.006	0.006	0.006
	MIN, MAX	NA, NA	14.130, 14.130	14.130, 14.130	0.006, 0.006	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	8.580, 4.502	10.560, 7.809	9.758, 6.248	0.009, NA	0.013, 0.011	0.011, NA
	SD, SE	7.1459, 1.7331	7.3937, 1.4787	7.2729, 1.1222	0.0092, 0.0017	0.0070, 0.0012	0.0082, 0.0011
	MEDIAN	7.509	9.204	9.066	0.006	0.012	0.012
	MIN, MAX	0.031, 26.177	0.345, 31.195	0.031, 31.195	0.000, 0.049	0.006, 0.031	0.000, 0.049
	5%, 95%	0.031, 26.177	2.201, 25.751	0.660, 25.751	0.000, 0.018	0.006, 0.031	0.000, 0.025
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.012, 0.012	0.012, 0.012
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.012	0.012
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.012, 0.012	0.012, 0.012
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6.638, 4.885	6.638, 4.885	0.012, 0.012	NA, NA	0.012, 0.012
	SD, SE	NA, NA	6.5224, 3.7657	6.5224, 3.7657	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.027	3.027	0.012	NA	0.012
	MIN, MAX	NA, NA	2.719, 14.167	2.719, 14.167	0.012, 0.012	NA, NA	0.012, 0.012
	5%, 95%	NA, NA	2.719, 14.167	2.719, 14.167	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11.243, 11.243	11.243, 11.243	0.006, 0.006	0.004, 0.003	0.005, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0028, 0.0020	0.0023, 0.0013
	MEDIAN	NA	11.243	11.243	0.006	0.004	0.006
	MIN, MAX	NA, NA	11.243, 11.243	11.243, 11.243	0.006, 0.006	0.002, 0.006	0.002, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.006	0.002, 0.006
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	9.107, 5.684	9.895, 6.575	9.587, 6.211	0.038, NA	0.013, 0.011	0.024, NA
	SD, SE	8.1155, 1.9128	7.9677, 1.5058	7.9450, 1.1714	0.1276, 0.0241	0.0075, 0.0013	0.0867, 0.0111
	MEDIAN	7.627	8.394	8.328	0.007	0.012	0.010
	MIN, MAX	0.070, 36.164	0.373, 33.503	0.070, 36.164	0.000, 0.682	0.006, 0.041	0.000, 0.682
	5%, 95%	0.070, 36.164	0.734, 25.067	0.734, 25.067	0.002, 0.094	0.006, 0.025	0.004, 0.039
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.014, 0.014	0.014, 0.014
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.014	0.014
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.014, 0.014	0.014, 0.014
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5.624, 3.867	5.624, 3.867	0.008, 0.008	NA, NA	0.008, 0.008
	SD, SE	NA, NA	5.8862, 3.3984	5.8862, 3.3984	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.850	2.850	0.008	NA	0.008
	MIN, MAX	NA, NA	1.638, 12.385	1.638, 12.385	0.008, 0.008	NA, NA	0.008, 0.008
	5%, 95%	NA, NA	1.638, 12.385	1.638, 12.385	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537612

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 33 of ?)

Lab: Harrogate
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4416.770, 4416.770	4416.770, 4416.770	3.000, 3.000	1.085, 0.955	1.723, 1.399
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.7283, 0.5150	1.2197, 0.7042
	MEDIAN	NA	4416.770	4416.770	3.000	1.085	1.600
	MIN, MAX	NA, NA	4416.768, 4416.768	4416.768, 4416.768	3.000, 3.000	0.570, 1.600	0.570, 3.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.570, 1.600	0.570, 3.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4697.130, 3151.040	4817.960, 3596.950	4770.680, 3415.400	7.754, 3.536	3.491, 2.546	5.448, 2.960
	SD, SE	3405.8700, 802.7700	2782.5300, 525.8480	3005.2000, 443.0930	11.2840, 2.1325	4.1073, 0.7150	8.4193, 1.0780
	MEDIAN	4337.910	4684.590	4563.560	1.985	2.565	2.265
	MIN, MAX	44.556, 14394.338	100.100, 10349.625	44.556, 14394.338	0.950, 46.593	0.800, 20.150	0.800, 46.593
	5%, 95%	44.556, 14394.300	720.720, 9396.410	720.720, 9396.410	1.030, 31.240	1.140, 16.174	1.140, 23.940
	BLQ Values Included	0	0	0	10	21	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8.631, 8.631	8.631, 8.631
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8.631	8.631
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8.631, 8.631	8.631, 8.631
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6683.610, 3225.040	6683.610, 3225.040	1.053, 1.053	NA, NA	1.053, 1.053
	SD, SE	NA, NA	9032.6000, 5214.9700	9032.6000, 5214.9700	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1939.840	1939.840	1.053	NA	1.053
	MIN, MAX	NA, NA	1011.230, 17099.775	1011.230, 17099.775	1.053, 1.053	NA, NA	1.053, 1.053
	5%, 95%	NA, NA	1011.230, 17099.800	1011.230, 17099.800	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537613

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 34 of 7)

Lab: Harrogate
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	5108.530, 5108.530	5108.530, 5108.530	2.750, 2.750	1.082, 1.070	1.638, 1.466
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.2234, 0.1580	0.9759, 0.5634
	MEDIAN	NA	5108.530	5108.530	2.750	1.082	1.240
	MIN, MAX	NA, NA	5108.532, 5108.532	5108.532, 5108.532	2.750, 2.750	0.924, 1.240	0.924, 2.750
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.924, 1.240	0.924, 2.750
	BLQ Values Included	NA	0	0	1	1	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	4529.450, 3076.860	5305.200, 4273.210	4994.900, 3747.100	9.759, 3.949	3.870, 2.904	6.573, 3.344
	SD, SE	2787.8400, 657.1010	3085.6400, 593.8320	2962.5500, 441.6310	18.4188, 3.4808	3.4189, 0.5952	12.9481, 1.6578
	MEDIAN	4738.130	5184.730	5068.690	3.216	2.500	2.875
	MIN, MAX	25.650, 11710.980	240.900, 16352.593	25.650, 16352.593	0.625, 95.190	0.750, 13.755	0.625, 95.190
	5%, 95%	25.650, 11711.000	980.947, 8761.660	980.947, 8761.660	0.820, 27.225	0.915, 12.760	0.915, 17.978
	BLQ Values Included	0	0	0	10	20	30
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10.725, 10.725	10.725, 10.725
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10.725	10.725
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10.725, 10.725	10.725, 10.725
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5394.560, 2348.630	5394.560, 2348.630	1.525, 1.525	NA, NA	1.525, 1.525
	SD, SE	NA, NA	7637.3700, 4409.4400	7637.3700, 4409.4400	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1239.350	1239.350	1.525	NA	1.525
	MIN, MAX	NA, NA	735.694, 14208.645	735.694, 14208.645	1.525, 1.525	NA, NA	1.525, 1.525
	5%, 95%	NA, NA	735.694, 14208.600	735.694, 14208.600	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537614

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 35 of 7)

Lab: Harrogate
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4753.000, 4753.000	4753.000, 4753.000	2.910, 2.910	1.559, 1.480	2.009, 1.854
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.6944, 0.4910	0.9217, 0.5321
	MEDIAN	NA	4753.000	4753.000	2.910	1.559	2.050
	MIN, MAX	NA, NA	4753.001, 4753.001	4753.001, 4753.001	2.910, 2.910	1.068, 2.050	1.068, 2.910
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.068, 2.050	1.068, 2.910
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	5082.500, 3029.690	5389.880, 4609.090	5265.470, 3889.200	6.864, 3.810	2.877, 2.438	4.707, 2.993
	SD, SE	3857.0400, 935.4700	2503.5300, 500.7050	3081.8400, 475.5390	9.9827, 1.8866	2.0788, 0.3619	7.1527, 0.9158
	MEDIAN	3803.840	5332.210	5189.440	2.654	2.450	2.500
	MIN, MAX	21.379, 13322.126	520.428, 10294.830	21.379, 13322.126	1.350, 43.940	0.990, 11.925	0.990, 43.940
	5%, 95%	21.379, 13322.100	1337.500, 9606.210	538.890, 10641.300	1.430, 33.930	1.034, 7.144	1.260, 14.104
	BLQ Values Included	0	0	0	12	24	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	15.268, 15.268	15.268, 15.268
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	15.268	15.268
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	15.268, 15.268	15.268, 15.268
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2776.790, 1605.730	2776.790, 1605.730	1.430, 1.430	NA, NA	1.430, 1.430
	SD, SE	NA, NA	3453.8500, 1994.0800	3453.8500, 1994.0800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	809.248	809.248	1.430	NA	1.430
	MIN, MAX	NA, NA	756.280, 6764.828	756.280, 6764.828	1.430, 1.430	NA, NA	1.430, 1.430
	5%, 95%	NA, NA	756.280, 6764.830	756.280, 6764.830	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537615

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4759.430, 4759.430	4759.430, 4759.430	2.887, 2.887	1.242, 1.241	1.790, 1.644
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0863, 0.0610	0.9517, 0.5495
	MEDIAN	NA	4759.430	4759.430	2.887	1.242	1.303
	MIN, MAX	NA, NA	4759.430, 4759.430	4759.430, 4759.430	2.887, 2.887	1.181, 1.303	1.181, 2.887
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.181, 1.303	1.181, 2.887
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4774.450, 3201.350	5019.730, 4083.070	4923.750, 3712.310	8.126, 4.140	3.413, 2.771	5.576, 3.332
	SD, SE	3149.1200, 742.2560	2632.2100, 497.4400	2813.9200, 414.8900	11.2987, 2.1353	2.6906, 0.4684	8.1802, 1.0474
	MEDIAN	4549.290	5302.910	5168.870	2.795	2.632	2.658
	MIN, MAX	30.528, 13142.500	287.143, 10962.600	30.528, 13142.500	1.133, 48.539	0.967, 11.705	0.967, 48.539
	5%, 95%	30.528, 13142.500	1109.300, 9136.210	1041.970, 9136.210	1.193, 30.177	1.167, 11.360	1.193, 21.198
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	11.541, 11.541	11.541, 11.541
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	11.541	11.541
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	11.541, 11.541	11.541, 11.541
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4951.660, 2414.640	4951.660, 2414.640	1.336, 1.336	NA, NA	1.336, 1.336
	SD, SE	NA, NA	6707.1200, 3872.3600	6707.1200, 3872.3600	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1329.480	1329.480	1.336	NA	1.336
	MIN, MAX	NA, NA	834.401, 12691.100	834.401, 12691.100	1.336, 1.336	NA, NA	1.336, 1.336
	5%, 95%	NA, NA	834.401, 12691.100	834.401, 12691.100	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537616

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	25065.200, 25065.200	25065.200, 25065.200	17.025, 17.025	6.158, 5.420	9.780, 7.937
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.1330, 2.9225	6.9216, 3.9962
	MEDIAN	NA	25065.200	25065.200	17.025	6.158	9.080
	MIN, MAX	NA, NA	25065.158, 25065.158	25065.158, 25065.158	17.025, 17.025	3.235, 9.080	3.235, 17.025
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.235, 9.080	3.235, 17.025
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	26656.200, 17882.100	27341.900, 20412.700	27073.600, 19382.400	44.006, 20.069	19.810, 14.448	30.916, 16.801
	SD, SE	19328.3000, 4555.7200	15790.8000, 2984.1900	17054.5000, 2514.5500	64.0366, 12.1018	23.3090, 4.0576	47.7795, 6.1175
	MEDIAN	24617.600	26585.100	25898.200	11.265	14.556	12.854
	MIN, MAX	252.855, 81687.868	568.068, 58734.122	252.855, 81687.868	5.391, 264.415	4.540, 114.351	4.540, 264.415
	5%, 95%	252.855, 81687.900	4090.090, 53324.600	4090.090, 53324.600	5.845, 177.287	6.470, 91.787	6.470, 135.860
	BLQ Values Included	0	0	0	10	21	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	48.981, 48.981	48.981, 48.981
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	48.981	48.981
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	48.981, 48.981	48.981, 48.981
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	37929.500, 18302.100	37929.500, 18302.100	5.976, 5.976	NA, NA	5.976, 5.976
	SD, SE	NA, NA	51260.0000, 29595.0000	51260.0000, 29595.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	11008.600	11008.600	5.976	NA	5.976
	MIN, MAX	NA, NA	5738.730, 97041.223	5738.730, 97041.223	5.976, 5.976	NA, NA	5.976, 5.976
	5%, 95%	NA, NA	5738.730, 97041.200	5738.730, 97041.200	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537617

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	28990.900, 28990.900	28990.900, 28990.900	15.606, 15.606	6.141, 6.075	9.296, 8.320
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.2678, 0.8965	5.5380, 3.1973
	MEDIAN	NA	28990.900	28990.900	15.606	6.141	7.037
	MIN, MAX	NA, NA	28990.919, 28990.919	28990.919, 28990.919	15.606, 15.606	5.244, 7.037	5.244, 15.606
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.244, 7.037	5.244, 15.606
	BLQ Values Included	NA	0	0	1	1	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	25704.700, 17461.200	30107.000, 24250.500	28346.100, 21264.800	55.383, 22.413	21.961, 16.480	37.303, 18.978
	SD, SE	15821.0000, 3729.0500	17511.0000, 3370.0000	16812.5000, 2506.2600	104.5260, 19.7536	19.4022, 3.3775	73.4805, 9.4082
	MEDIAN	26888.900	29423.400	28764.800	18.251	14.188	16.316
	MIN, MAX	145.564, 66459.812	1367.108, 92800.965	145.564, 92800.965	3.547, 540.203	4.256, 78.060	3.547, 540.203
	5%, 95%	145.564, 66459.800	5566.870, 49722.400	5566.870, 49722.400	4.654, 154.502	5.193, 72.413	5.193, 102.025
	BLQ Values Included	0	0	0	10	20	30
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	60.864, 60.864	60.864, 60.864
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	60.864	60.864
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	60.864, 60.864	60.864, 60.864
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	30614.100, 13328.500	30614.100, 13328.500	8.654, 8.654	NA, NA	8.654, 8.654
	SD, SE	NA, NA	43342.1000, 25023.6000	43342.1000, 25023.6000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7033.320	7033.320	8.654	NA	8.654
	MIN, MAX	NA, NA	4175.063, 80634.060	4175.063, 80634.060	8.654, 8.654	NA, NA	8.654, 8.654
	5%, 95%	NA, NA	4175.060, 80634.100	4175.060, 80634.100	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	26973.300, 26973.300	26973.300, 26973.300	16.514, 16.514	8.848, 8.397	11.403, 10.521
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	3.9407, 2.7865	5.2303, 3.0197
	MEDIAN	NA	26973.300	26973.300	16.514	8.848	11.634
	MIN, MAX	NA, NA	26973.281, 26973.281	26973.281, 26973.281	16.514, 16.514	6.061, 11.634	6.061, 16.514
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.061, 11.634	6.061, 16.514
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	28843.200, 17193.500	30587.600, 26156.600	29881.500, 22071.200	38.951, 21.619	16.329, 13.838	26.713, 16.983
	SD, SE	21888.7000, 5308.7900	14207.5000, 2841.5000	17489.5000, 2698.6800	56.6519, 10.7062	11.7969, 2.0536	40.5914, 5.1972
	MEDIAN	21586.800	30260.300	29450.100	15.062	13.904	14.188
	MIN, MAX	121.326, 75603.065	2953.429, 58423.160	121.326, 75603.065	7.661, 249.360	5.618, 67.674	5.618, 249.360
	5%, 95%	121.326, 75603.100	7590.290, 54515.200	3058.200, 60389.500	8.115, 192.553	5.868, 40.542	7.151, 80.040
	BLQ Values Included	0	0	0	12	24	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	86.646, 86.646	86.646, 86.646
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	86.646	86.646
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	86.646, 86.646	86.646, 86.646
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	15758.300, 9112.540	15758.300, 9112.540	8.115, 8.115	NA, NA	8.115, 8.115
	SD, SE	NA, NA	19600.6000, 11316.4000	19600.6000, 11316.4000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4592.480	4592.480	8.115	NA	8.115
	MIN, MAX	NA, NA	4291.889, 38390.399	4291.889, 38390.399	8.115, 8.115	NA, NA	8.115, 8.115
	5%, 95%	NA, NA	4291.890, 38390.400	4291.890, 38390.400	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537619

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	27009.800, 27009.800	27009.800, 27009.800	16.382, 16.382	7.049, 7.040	10.160, 9.329
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4872, 0.3445	5.3997, 3.1175
	MEDIAN	NA	27009.800	27009.800	16.382	7.049	7.393
	MIN, MAX	NA, NA	27009.800, 27009.800	27009.800, 27009.800	16.382, 16.382	6.704, 7.393	6.704, 16.382
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.704, 7.393	6.704, 16.382
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	27095.000, 18167.700	28487.000, 23171.400	27942.300, 21067.400	46.113, 23.493	19.367, 15.726	31.644, 18.908
	SD, SE	17871.3000, 4212.3000	14937.8000, 2822.9700	15969.0000, 2354.5000	64.1202, 12.1176	15.2687, 2.6579	46.4228, 5.9438
	MEDIAN	25817.200	30094.000	29333.300	15.859	14.935	15.082
	MIN, MAX	173.248, 74583.600	1629.540, 62212.600	173.248, 74583.600	6.432, 275.461	5.486, 66.424	5.486, 275.461
	5%, 95%	173.248, 74583.600	6295.300, 51848.000	5913.160, 51848.000	6.772, 171.255	6.621, 64.466	6.772, 120.299
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	65.497, 65.497	65.497, 65.497
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	65.497	65.497
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	65.497, 65.497	65.497, 65.497
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	28100.600, 13703.100	28100.600, 13703.100	7.582, 7.582	NA, NA	7.582, 7.582
	SD, SE	NA, NA	38062.9000, 21975.6000	38062.9000, 21975.6000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7544.790	7544.790	7.582	NA	7.582
	MIN, MAX	NA, NA	4735.230, 72021.900	4735.230, 72021.900	7.582, 7.582	NA, NA	7.582, 7.582
	5%, 95%	NA, NA	4735.230, 72021.900	4735.230, 72021.900	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537620

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 41 of 7)

Lab: Harrogate
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.019, 3.019	3.019, 3.019	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	3.019	3.019	0.001	0.001	0.001
	MIN, MAX	NA, NA	3.019, 3.019	3.019, 3.019	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3.409, 2.384	4.319, 3.236	3.963, 2.871	0.005, NA	0.003, 0.002	0.004, NA
	SD, SE	2.1337, 0.5029	2.3375, 0.4417	2.2804, 0.3362	0.0076, 0.0014	0.0034, 0.0006	0.0058, 0.0007
	MEDIAN	3.233	4.312	3.935	0.001	0.002	0.002
	MIN, MAX	0.042, 8.403	0.083, 8.958	0.042, 8.958	0.000, 0.033	0.001, 0.015	0.000, 0.033
	5%, 95%	0.042, 8.403	0.473, 8.183	0.473, 8.183	0.001, 0.021	0.001, 0.014	0.001, 0.015
	BLQ Values Included	0	0	0	10	21	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.010, 0.010	0.010, 0.010
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.010	0.010
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.010, 0.010	0.010, 0.010
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.178, 2.280	4.178, 2.280	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	5.3657, 3.0979	5.3657, 3.0979	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.251	1.251	0.001	NA	0.001
	MIN, MAX	NA, NA	0.913, 10.371	0.913, 10.371	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.913, 10.371	0.913, 10.371	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537621

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.495, 3.495	3.495, 3.495	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	3.495	3.495	0.001	0.001	0.001
	MIN, MAX	NA, NA	3.495, 3.495	3.495, 3.495	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.001
	BLQ Values Included	NA	0	0	1	1	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	3.265, 2.263	4.223, 3.368	3.840, 2.873	0.007, NA	0.003, 0.002	0.005, NA
	SD, SE	1.9738, 0.4652	2.6240, 0.5050	2.4081, 0.3590	0.0170, 0.0032	0.0023, 0.0004	0.0117, 0.0015
	MEDIAN	2.968	3.831	3.720	0.002	0.002	0.002
	MIN, MAX	0.029, 7.522	0.240, 12.831	0.029, 12.831	0.000, 0.091	0.001, 0.009	0.000, 0.091
	5%, 95%	0.029, 7.522	0.768, 8.239	0.690, 8.058	0.001, 0.015	0.001, 0.008	0.001, 0.009
	BLQ Values Included	0	0	0	10	20	30
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.015, 0.015	0.015, 0.015
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.015	0.015
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.015, 0.015	0.015, 0.015
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.984, 2.092	3.984, 2.092	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	5.0997, 2.9443	5.0997, 2.9443	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.462	1.462	0.001	NA	0.001
	MIN, MAX	NA, NA	0.636, 9.853	0.636, 9.853	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.636, 9.853	0.636, 9.853	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537622

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.862, 2.862	2.862, 2.862	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	2.862	2.862	0.001	0.001	0.001
	MIN, MAX	NA, NA	2.862, 2.862	2.862, 2.862	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	3.363, 2.188	4.493, 3.795	4.036, 3.037	0.004, 0.002	0.003, 0.002	0.003, 0.002
	SD, SE	2.1802, 0.5288	2.3803, 0.4761	2.3424, 0.3614	0.0056, 0.0011	0.0018, 0.0003	0.0040, 0.0005
	MEDIAN	2.961	3.958	3.754	0.002	0.002	0.002
	MIN, MAX	0.019, 7.284	0.518, 10.517	0.019, 10.517	0.001, 0.025	0.001, 0.008	0.001, 0.025
	5%, 95%	0.019, 7.284	0.892, 9.415	0.892, 8.316	0.001, 0.019	0.001, 0.007	0.001, 0.008
	BLQ Values Included	0	0	0	12	24	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.020, 0.020	0.020, 0.020
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.020	0.020
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.020, 0.020	0.020, 0.020
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.527, 2.063	4.527, 2.063	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	6.3498, 3.6660	6.3498, 3.6660	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.890	0.890	0.002	NA	0.002
	MIN, MAX	NA, NA	0.832, 11.859	0.832, 11.859	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	0.832, 11.859	0.832, 11.859	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.125, 3.125	3.125, 3.125	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	3.125	3.125	0.001	0.001	0.001
	MIN, MAX	NA, NA	3.125, 3.125	3.125, 3.125	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.001
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3.344, 2.331	4.340, 3.506	3.950, 2.989	0.005, 0.003	0.003, 0.002	0.004, 0.002
	SD, SE	2.0124, 0.4743	2.3432, 0.4428	2.2508, 0.3319	0.0086, 0.0016	0.0022, 0.0004	0.0061, 0.0008
	MEDIAN	3.191	4.104	3.840	0.002	0.002	0.002
	MIN, MAX	0.030, 7.123	0.280, 8.923	0.030, 8.923	0.001, 0.042	0.001, 0.010	0.001, 0.042
	5%, 95%	0.030, 7.123	0.733, 8.810	0.733, 8.763	0.001, 0.018	0.001, 0.009	0.001, 0.010
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.015, 0.015	0.015, 0.015
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.015	0.015
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.015, 0.015	0.015, 0.015
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.230, 2.174	4.230, 2.174	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	5.6013, 3.2339	5.6013, 3.2339	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.182	1.182	0.001	NA	0.001
	MIN, MAX	NA, NA	0.813, 10.694	0.813, 10.694	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.813, 10.694	0.813, 10.694	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17.133, 17.133	17.133, 17.133	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	17.133	17.133	0.006	0.003	0.006
	MIN, MAX	NA, NA	17.133, 17.133	17.133, 17.133	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	19.343, 13.527	24.512, 18.365	22.489, 16.294	0.027, NA	0.017, 0.013	0.022, NA
	SD, SE	12.1086, 2.8540	13.2651, 2.5069	12.9411, 1.9081	0.0432, 0.0082	0.0193, 0.0034	0.0326, 0.0042
	MEDIAN	18.345	24.471	22.329	0.006	0.011	0.011
	MIN, MAX	0.238, 47.687	0.471, 50.837	0.238, 50.837	0.000, 0.187	0.006, 0.085	0.000, 0.187
	5%, 95%	0.238, 47.687	2.684, 46.439	2.684, 46.439	0.006, 0.119	0.006, 0.079	0.006, 0.085
	BLQ Values Included	0	0	0	10	21	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.057, 0.057	0.057, 0.057
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.057	0.057
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.057, 0.057	0.057, 0.057
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	23.712, 12.936	23.712, 12.936	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	30.4501, 17.5804	30.4501, 17.5804	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7.099	7.099	0.006	NA	0.006
	MIN, MAX	NA, NA	5.181, 58.855	5.181, 58.855	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	5.181, 58.855	5.181, 58.855	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	19.834, 19.834	19.834, 19.834	0.006, 0.006	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	19.834	19.834	0.006	0.006	0.006
	MIN, MAX	NA, NA	19.834, 19.834	19.834, 19.834	0.006, 0.006	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	BLQ Values Included	NA	0	0	1	1	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	18.530, 12.843	23.966, 19.115	21.791, 16.304	0.040, NA	0.018, 0.014	0.028, NA
	SD, SE	11.2015, 2.6402	14.8911, 2.8658	13.6661, 2.0372	0.0961, 0.0182	0.0131, 0.0023	0.0662, 0.0085
	MEDIAN	16.841	21.741	21.111	0.011	0.011	0.011
	MIN, MAX	0.165, 42.687	1.362, 72.816	0.165, 72.816	0.000, 0.516	0.006, 0.051	0.000, 0.516
	5%, 95%	0.165, 42.687	4.358, 46.756	3.916, 45.729	0.006, 0.085	0.006, 0.045	0.006, 0.051
	BLQ Values Included	0	0	0	10	20	30
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.085, 0.085	0.085, 0.085
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.085	0.085
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.085, 0.085	0.085, 0.085
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	22.607, 11.874	22.607, 11.874	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	28.9412, 16.7092	28.9412, 16.7092	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	8.297	8.297	0.006	NA	0.006
	MIN, MAX	NA, NA	3.609, 55.916	3.609, 55.916	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	3.609, 55.916	3.609, 55.916	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	16.242, 16.242	16.242, 16.242	0.006, 0.006	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	16.242	16.242	0.006	0.006	0.006
	MIN, MAX	NA, NA	16.242, 16.242	16.242, 16.242	0.006, 0.006	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	19.086, 12.417	25.499, 21.536	22.903, 17.233	0.022, 0.013	0.015, 0.013	0.018, 0.013
	SD, SE	12.3729, 3.0009	13.5081, 2.7016	13.2929, 2.0511	0.0315, 0.0060	0.0104, 0.0018	0.0227, 0.0029
	MEDIAN	16.804	22.462	21.304	0.011	0.011	0.011
	MIN, MAX	0.108, 41.337	2.940, 59.684	0.108, 59.684	0.006, 0.142	0.006, 0.045	0.006, 0.142
	5%, 95%	0.108, 41.337	5.062, 53.430	5.062, 47.193	0.006, 0.108	0.006, 0.040	0.006, 0.045
	BLQ Values Included	0	0	0	12	24	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.114, 0.114	0.114, 0.114
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.114	0.114
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.114, 0.114	0.114, 0.114
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	25.691, 11.709	25.691, 11.709	0.011, 0.011	NA, NA	0.011, 0.011
	SD, SE	NA, NA	36.0348, 20.8047	36.0348, 20.8047	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5.051	5.051	0.011	NA	0.011
	MIN, MAX	NA, NA	4.722, 67.300	4.722, 67.300	0.011, 0.011	NA, NA	0.011, 0.011
	5%, 95%	NA, NA	4.722, 67.300	4.722, 67.300	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17.736, 17.736	17.736, 17.736	0.006, 0.006	0.005, 0.005	0.005, 0.005
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0014, 0.0010	0.0012, 0.0007
	MEDIAN	NA	17.736	17.736	0.006	0.005	0.006
	MIN, MAX	NA, NA	17.736, 17.736	17.736, 17.736	0.006, 0.006	0.004, 0.006	0.004, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.004, 0.006	0.004, 0.006
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	18.974, 13.230	24.628, 19.898	22.416, 16.961	0.030, 0.015	0.017, 0.014	0.023, 0.014
	SD, SE	11.4205, 2.6918	13.2975, 2.5130	12.7730, 1.8833	0.0488, 0.0092	0.0124, 0.0022	0.0346, 0.0044
	MEDIAN	18.107	23.289	21.789	0.011	0.011	0.011
	MIN, MAX	0.170, 40.425	1.591, 50.636	0.170, 50.636	0.004, 0.240	0.006, 0.057	0.004, 0.240
	5%, 95%	0.170, 40.425	4.162, 49.999	4.162, 49.730	0.004, 0.104	0.006, 0.051	0.006, 0.057
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.085, 0.085	0.085, 0.085
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.085	0.085
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.085, 0.085	0.085, 0.085
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	24.003, 12.337	24.003, 12.337	0.008, 0.008	NA, NA	0.008, 0.008
	SD, SE	NA, NA	31.7888, 18.3533	31.7888, 18.3533	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	6.706	6.706	0.008	NA	0.008
	MIN, MAX	NA, NA	4.614, 60.690	4.614, 60.690	0.008, 0.008	NA, NA	0.008, 0.008
	5%, 95%	NA, NA	4.614, 60.690	4.614, 60.690	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537628

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2357.630, 2357.630	2357.630, 2357.630	3.000, 3.000	1.085, 0.955	1.723, 1.399
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.7283, 0.5150	1.2197, 0.7042
	MEDIAN	NA	2357.630	2357.630	3.000	1.085	1.600
	MIN, MAX	NA, NA	2357.632, 2357.632	2357.632, 2357.632	3.000, 3.000	0.570, 1.600	0.570, 3.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.570, 1.600	0.570, 3.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1683.980, 1226.760	1714.800, 1315.120	1702.740, 1279.810	4.350, 2.329	2.313, 2.015	3.248, 2.154
	SD, SE	920.8080, 217.0360	998.0710, 188.6180	958.2440, 141.2850	6.4518, 1.2193	1.4071, 0.2449	4.5646, 0.5844
	MEDIAN	1908.820	1583.010	1795.820	1.830	1.950	1.930
	MIN, MAX	26.790, 3201.831	50.050, 3606.938	26.790, 3606.938	0.530, 27.900	0.800, 6.912	0.530, 27.900
	5%, 95%	26.790, 3201.830	308.979, 3580.190	308.979, 3472.250	0.715, 20.140	0.960, 6.825	0.800, 12.160
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	3.014, 3.014	3.014, 3.014
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	3.014	3.014
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	3.014, 3.014	3.014, 3.014
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2769.410, 1779.810	2769.410, 1779.810	0.810, 0.810	NA, NA	0.810, 0.810
	SD, SE	NA, NA	3175.1600, 1833.1800	3175.1600, 1833.1800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	960.224	960.224	0.810	NA	0.810
	MIN, MAX	NA, NA	912.340, 6435.660	912.340, 6435.660	0.810, 0.810	NA, NA	0.810, 0.810
	5%, 95%	NA, NA	912.340, 6435.660	912.340, 6435.660	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537629

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1918.490, 1918.490	1918.490, 1918.490	2.750, 2.750	0.950, 0.905	1.550, 1.310
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4101, 0.2900	1.0789, 0.6229
	MEDIAN	NA	1918.490	1918.490	2.750	0.950	1.240
	MIN, MAX	NA, NA	1918.488, 1918.488	1918.488, 1918.488	2.750, 2.750	0.660, 1.240	0.660, 2.750
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.660, 1.240	0.660, 2.750
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1784.290, 1256.440	1827.050, 1440.430	1809.940, 1363.810	5.415, 2.589	2.415, 2.158	3.792, 2.346
	SD, SE	902.3150, 212.6780	1113.1100, 214.2190	1023.3100, 152.5460	11.1110, 2.0998	1.2745, 0.2219	7.6610, 0.9809
	MEDIAN	1769.270	1686.630	1731.970	1.917	2.210	2.200
	MIN, MAX	13.950, 3133.273	148.738, 4252.954	13.950, 4252.954	0.625, 59.280	0.750, 7.795	0.625, 59.280
	5%, 95%	13.950, 3133.270	350.900, 3766.020	226.118, 3463.250	0.815, 13.221	0.915, 4.272	0.820, 9.804
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	4.875, 4.875	4.875, 4.875
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	4.875	4.875
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	4.875, 4.875	4.875, 4.875
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1901.200, 1249.340	1901.200, 1249.340	1.525, 1.525	NA, NA	1.525, 1.525
	SD, SE	NA, NA	2135.3900, 1232.8700	2135.3900, 1232.8700	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	680.884	680.884	1.525	NA	1.525
	MIN, MAX	NA, NA	655.832, 4366.890	655.832, 4366.890	1.525, 1.525	NA, NA	1.525, 1.525
	5%, 95%	NA, NA	655.832, 4366.890	655.832, 4366.890	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1616.420, 1616.420	1616.420, 1616.420	2.910, 2.910	1.559, 1.480	2.009, 1.854
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.6944, 0.4910	0.9217, 0.5321
	MEDIAN	NA	1616.420	1616.420	2.910	1.559	2.050
	MIN, MAX	NA, NA	1616.418, 1616.418	1616.418, 1616.418	2.910, 2.910	1.068, 2.050	1.068, 2.910
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.068, 2.050	1.068, 2.910
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	2040.610, 1231.980	1992.530, 1661.200	2011.990, 1471.890	3.926, 2.498	2.184, 2.042	2.983, 2.240
	SD, SE	1576.8000, 382.4300	1143.3100, 228.6630	1317.5700, 203.3060	5.3968, 1.0199	0.8149, 0.1419	3.7719, 0.4829
	MEDIAN	1600.540	1714.570	1652.450	2.032	2.050	2.050
	MIN, MAX	6.393, 5162.740	225.246, 4886.167	6.393, 5162.740	0.750, 25.870	0.940, 4.740	0.750, 25.870
	5%, 95%	6.393, 5162.740	573.712, 3866.580	354.936, 4856.040	1.072, 15.370	0.990, 3.350	1.072, 7.188
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.420, 6.420	6.420, 6.420
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.420	6.420
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.420, 6.420	6.420, 6.420
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1251.920, 905.829	1251.920, 905.829	1.430, 1.430	NA, NA	1.430, 1.430
	SD, SE	NA, NA	1219.3000, 703.9640	1219.3000, 703.9640	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	716.800	716.800	1.430	NA	1.430
	MIN, MAX	NA, NA	391.688, 2647.285	391.688, 2647.285	1.430, 1.430	NA, NA	1.430, 1.430
	5%, 95%	NA, NA	391.688, 2647.290	391.688, 2647.290	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 52 of ?)

Lab: Harrogate
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1964.180, 1964.180	1964.180, 1964.180	2.887, 2.887	1.198, 1.193	1.761, 1.602
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.1485, 0.1050	0.9808, 0.5663
	MEDIAN	NA	1964.180	1964.180	2.887	1.198	1.303
	MIN, MAX	NA, NA	1964.180, 1964.180	1964.180, 1964.180	2.887, 2.887	1.093, 1.303	1.093, 2.887
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.093, 1.303	1.093, 2.887
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1830.020, 1303.960	1797.060, 1460.550	1809.960, 1397.160	4.564, 2.657	2.304, 2.119	3.341, 2.351
	SD, SE	1019.6400, 240.3310	1011.7600, 191.2050	1003.6100, 147.9740	6.4657, 1.2219	0.9723, 0.1692	4.5393, 0.5812
	MEDIAN	1786.240	1681.960	1695.440	1.991	2.223	2.150
	MIN, MAX	15.711, 3774.690	141.345, 3982.290	15.711, 3982.290	0.787, 30.043	0.967, 5.145	0.787, 30.043
	5%, 95%	15.711, 3774.690	374.266, 3584.060	374.266, 3584.060	1.092, 16.027	0.980, 4.381	1.092, 12.202
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	4.770, 4.770	4.770, 4.770
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	4.770	4.770
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	4.770, 4.770	4.770, 4.770
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1974.180, 1322.640	1974.180, 1322.640	1.255, 1.255	NA, NA	1.255, 1.255
	SD, SE	NA, NA	2173.3500, 1254.7900	2173.3500, 1254.7900	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	761.657	761.657	1.255	NA	1.255
	MIN, MAX	NA, NA	677.599, 4483.280	677.599, 4483.280	1.255, 1.255	NA, NA	1.255, 1.255
	5%, 95%	NA, NA	677.599, 4483.280	677.599, 4483.280	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13379.600, 13379.600	13379.600, 13379.600	17.025, 17.025	6.158, 5.420	9.780, 7.937
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.1330, 2.9225	6.9216, 3.9962
	MEDIAN	NA	13379.600	13379.600	17.025	6.158	9.080
	MIN, MAX	NA, NA	13379.562, 13379.562	13379.562, 13379.562	17.025, 17.025	3.235, 9.080	3.235, 17.025
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.235, 9.080	3.235, 17.025
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	9556.570, 6961.840	9731.500, 7463.300	9663.050, 7262.920	24.688, 13.220	13.125, 11.436	18.432, 12.223
	SD, SE	5225.5800, 1231.6800	5664.0600, 1070.4100	5438.0400, 801.7950	36.6142, 6.9194	7.9851, 1.3900	25.9042, 3.3167
	MEDIAN	10832.500	8983.560	10191.300	10.383	11.066	10.953
	MIN, MAX	152.033, 18170.391	284.034, 20469.373	152.033, 20469.373	3.008, 158.333	4.540, 39.226	3.008, 158.333
	5%, 95%	152.033, 18170.400	1753.460, 20317.600	1753.460, 19705.000	4.058, 114.295	5.448, 38.732	4.540, 69.008
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	17.104, 17.104	17.104, 17.104
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	17.104	17.104
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	17.104, 17.104	17.104, 17.104
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	15716.400, 10100.400	15716.400, 10100.400	4.597, 4.597	NA, NA	4.597, 4.597
	SD, SE	NA, NA	18019.0000, 10403.3000	18019.0000, 10403.3000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5449.270	5449.270	4.597	NA	4.597
	MIN, MAX	NA, NA	5177.530, 36522.371	5177.530, 36522.371	4.597, 4.597	NA, NA	4.597, 4.597
	5%, 95%	NA, NA	5177.530, 36522.400	5177.530, 36522.400	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10887.400, 10887.400	10887.400, 10887.400	15.606, 15.606	5.392, 5.134	8.796, 7.437
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.3271, 1.6455	6.1226, 3.5349
	MEDIAN	NA	10887.400	10887.400	15.606	5.392	7.037
	MIN, MAX	NA, NA	10887.419, 10887.419	10887.419, 10887.419	15.606, 15.606	3.746, 7.037	3.746, 15.606
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.746, 7.037	3.746, 15.606
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	10125.800, 7130.290	10368.500, 8174.460	10271.400, 7739.590	30.730, 14.693	13.708, 12.246	21.521, 13.314
	SD, SE	5120.6400, 1206.9500	6316.9200, 1215.6900	5807.2900, 865.6990	63.0547, 11.9162	7.2326, 1.2590	43.4765, 5.5666
	MEDIAN	10040.600	9571.630	9828.950	10.879	12.542	12.485
	MIN, MAX	79.166, 17781.324	844.088, 24135.514	79.166, 24135.514	3.547, 336.414	4.256, 44.237	3.547, 336.414
	5%, 95%	79.166, 17781.300	1991.360, 21372.200	1283.220, 19653.900	4.625, 75.029	5.193, 24.244	4.654, 55.638
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	27.666, 27.666	27.666, 27.666
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	27.666	27.666
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	27.666, 27.666	27.666, 27.666
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	10789.300, 7089.980	10789.300, 7089.980	8.654, 8.654	NA, NA	8.654, 8.654
	SD, SE	NA, NA	12118.3000, 6996.5100	12118.3000, 6996.5100	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3864.020	3864.020	8.654	NA	8.654
	MIN, MAX	NA, NA	3721.847, 24782.101	3721.847, 24782.101	8.654, 8.654	NA, NA	8.654, 8.654
	5%, 95%	NA, NA	3721.850, 24782.100	3721.850, 24782.100	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 55 of ?)

Lab: Harrogate
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	9173.170, 9173.170	9173.170, 9173.170	16.514, 16.514	8.848, 8.397	11.403, 10.521
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	3.9407, 2.7865	5.2303, 3.0197
	MEDIAN	NA	9173.170	9173.170	16.514	8.848	11.634
	MIN, MAX	NA, NA	9173.172, 9173.172	9173.172, 9173.172	16.514, 16.514	6.061, 11.634	6.061, 16.514
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.061, 11.634	6.061, 16.514
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	11580.500, 6991.470	11307.600, 9427.310	11418.000, 8352.990	22.280, 14.175	12.392, 11.590	16.931, 12.712
	SD, SE	8948.3300, 2170.2900	6488.3000, 1297.6600	7477.2300, 1153.7600	30.6269, 5.7879	4.6245, 0.8050	21.4054, 2.7407
	MEDIAN	9083.040	9730.190	9577.640	11.532	11.634	11.634
	MIN, MAX	36.280, 29298.550	1278.271, 27728.998	36.280, 29298.550	4.256, 146.812	5.335, 26.900	4.256, 146.812
	5%, 95%	36.280, 29298.600	3255.820, 21942.800	2014.260, 27558.000	6.084, 87.225	5.618, 19.011	6.084, 40.792
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	36.434, 36.434	36.434, 36.434
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	36.434	36.434
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	36.434, 36.434	36.434, 36.434
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	7104.670, 5140.580	7104.670, 5140.580	8.115, 8.115	NA, NA	8.115, 8.115
	SD, SE	NA, NA	6919.5400, 3995.0000	6919.5400, 3995.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4067.840	4067.840	8.115	NA	8.115
	MIN, MAX	NA, NA	2222.829, 15023.342	2222.829, 15023.342	8.115, 8.115	NA, NA	8.115, 8.115
	5%, 95%	NA, NA	2222.830, 15023.300	2222.830, 15023.300	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11146.700, 11146.700	11146.700, 11146.700	16.382, 16.382	6.799, 6.773	9.993, 9.092
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.8400, 0.5940	5.5645, 3.2127
	MEDIAN	NA	11146.700	11146.700	16.382	6.799	7.393
	MIN, MAX	NA, NA	11146.700, 11146.700	11146.700, 11146.700	16.382, 16.382	6.205, 7.393	6.205, 16.382
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.205, 7.393	6.205, 16.382
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	10385.400, 7399.990	10198.300, 8288.650	10271.500, 7928.860	25.899, 15.079	13.075, 12.027	18.961, 13.343
	SD, SE	5786.4600, 1363.8800	5741.7500, 1085.0900	5695.4600, 839.7500	36.6932, 6.9344	5.5178, 0.9605	25.7610, 3.2984
	MEDIAN	10136.900	9545.130	9621.610	11.298	12.617	12.201
	MIN, MAX	89.160, 21421.400	802.131, 22599.500	89.160, 22599.500	4.464, 170.495	5.486, 29.198	4.464, 170.496
	5%, 95%	89.160, 21421.400	2123.960, 20339.500	2123.960, 20339.500	6.195, 90.955	5.562, 24.864	6.195, 69.245
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	27.068, 27.068	27.068, 27.068
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	27.068	27.068
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	27.068, 27.068	27.068, 27.068
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	11203.500, 7506.000	11203.500, 7506.000	7.122, 7.122	NA, NA	7.122, 7.122
	SD, SE	NA, NA	12333.8000, 7120.9000	12333.8000, 7120.9000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4322.410	4322.410	7.122	NA	7.122
	MIN, MAX	NA, NA	3845.370, 25442.600	3845.370, 25442.600	7.122, 7.122	NA, NA	7.122, 7.122
	5%, 95%	NA, NA	3845.370, 25442.600	3845.370, 25442.600	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537636

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.611, 1.611	1.611, 1.611	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.611	1.611	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.611, 1.611	1.611, 1.611	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1.448, 0.928	1.691, 1.184	1.596, 1.076	0.003, NA	0.002, 0.002	0.002, NA
	SD, SE	1.3218, 0.3115	1.1528, 0.2179	1.2132, 0.1789	0.0043, 0.0008	0.0017, 0.0003	0.0031, 0.0004
	MEDIAN	1.260	1.701	1.401	0.001	0.002	0.002
	MIN, MAX	0.025, 5.808	0.042, 4.207	0.025, 5.808	0.000, 0.020	0.001, 0.010	0.000, 0.020
	5%, 95%	0.025, 5.808	0.203, 3.886	0.203, 3.886	0.000, 0.010	0.001, 0.005	0.001, 0.009
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.782, 1.258	1.782, 1.258	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	1.8397, 1.0621	1.8397, 1.0621	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.824	0.824	0.001	NA	0.001
	MIN, MAX	NA, NA	0.619, 3.903	0.619, 3.903	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.619, 3.903	0.619, 3.903	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.313, 1.313	1.313, 1.313	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.313	1.313	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.313, 1.313	1.313, 1.313	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1.431, 0.925	1.509, 1.135	1.478, 1.046	0.004, NA	0.002, 0.002	0.003, NA
	SD, SE	1.1733, 0.2765	1.0652, 0.2050	1.0972, 0.1636	0.0105, 0.0020	0.0011, 0.0002	0.0072, 0.0009
	MEDIAN	1.264	1.250	1.263	0.002	0.002	0.002
	MIN, MAX	0.016, 5.177	0.148, 4.123	0.016, 5.177	0.000, 0.057	0.001, 0.005	0.000, 0.057
	5%, 95%	0.016, 5.177	0.275, 3.337	0.148, 3.337	0.000, 0.007	0.001, 0.004	0.001, 0.005
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.007, 0.007	0.007, 0.007
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.007	0.007
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.007, 0.007	0.007, 0.007
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.466, 1.113	1.466, 1.113	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	1.3579, 0.7840	1.3579, 0.7840	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.803	0.803	0.001	NA	0.001
	MIN, MAX	NA, NA	0.567, 3.028	0.567, 3.028	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.567, 3.028	0.567, 3.028	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	0.973, 0.973	0.973, 0.973	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	0.973	0.973	0.001	0.001	0.001
	MIN, MAX	NA, NA	0.973, 0.973	0.973, 0.973	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1.378, 0.893	1.750, 1.368	1.599, 1.151	0.002, NA	0.002, 0.002	0.002, NA
	SD, SE	0.9164, 0.2223	1.2385, 0.2477	1.1224, 0.1732	0.0029, 0.0005	0.0011, 0.0002	0.0021, 0.0003
	MEDIAN	1.292	1.450	1.372	0.001	0.002	0.002
	MIN, MAX	0.006, 3.315	0.224, 5.186	0.006, 5.186	0.000, 0.014	0.001, 0.005	0.000, 0.014
	5%, 95%	0.006, 3.315	0.383, 4.005	0.383, 3.315	0.000, 0.009	0.001, 0.005	0.001, 0.005
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.009, 0.009	0.009, 0.009
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.009	0.009
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.009, 0.009	0.009, 0.009
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.962, 1.164	1.962, 1.164	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	2.3302, 1.3453	2.3302, 1.3453	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.843	0.843	0.002	NA	0.002
	MIN, MAX	NA, NA	0.403, 4.641	0.403, 4.641	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	0.403, 4.641	0.403, 4.641	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.299, 1.299	1.299, 1.299	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	1.299	1.299	0.001	0.001	0.001
	MIN, MAX	NA, NA	1.299, 1.299	1.299, 1.299	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1.412, 0.957	1.671, 1.257	1.570, 1.130	0.003, NA	0.002, 0.002	0.002, NA
	SD, SE	1.0606, 0.2500	1.1392, 0.2153	1.1045, 0.1629	0.0050, 0.0009	0.0011, 0.0002	0.0035, 0.0005
	MEDIAN	1.295	1.533	1.354	0.001	0.002	0.002
	MIN, MAX	0.016, 4.572	0.138, 4.505	0.016, 4.572	0.000, 0.026	0.001, 0.006	0.000, 0.026
	5%, 95%	0.016, 4.572	0.266, 3.886	0.266, 3.886	0.001, 0.009	0.001, 0.004	0.001, 0.007
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.006	0.006
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.737, 1.204	1.737, 1.204	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	1.8375, 1.0609	1.8375, 1.0609	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.745	0.745	0.001	NA	0.001
	MIN, MAX	NA, NA	0.608, 3.857	0.608, 3.857	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.608, 3.857	0.608, 3.857	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	9.142, 9.142	9.142, 9.142	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	9.142	9.142	0.006	0.003	0.006
	MIN, MAX	NA, NA	9.142, 9.142	9.142, 9.142	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	8.216, 5.264	9.595, 6.718	9.056, 6.107	0.016, NA	0.012, 0.010	0.014, NA
	SD, SE	7.5011, 1.7680	6.5422, 1.2364	6.8847, 1.0151	0.0242, 0.0046	0.0093, 0.0016	0.0177, 0.0023
	MEDIAN	7.151	9.650	7.951	0.006	0.011	0.011
	MIN, MAX	0.142, 32.960	0.238, 23.875	0.142, 32.960	0.000, 0.114	0.006, 0.057	0.000, 0.114
	5%, 95%	0.142, 32.960	1.152, 22.053	1.152, 22.053	0.000, 0.057	0.006, 0.028	0.006, 0.051
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.017, 0.017	0.017, 0.017
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.017	0.017
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.017, 0.017	0.017, 0.017
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	10.113, 7.139	10.113, 7.139	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	10.4406, 6.0279	10.4406, 6.0279	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4.676	4.676	0.006	NA	0.006
	MIN, MAX	NA, NA	3.513, 22.150	3.513, 22.150	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	3.513, 22.150	3.513, 22.150	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	7.451, 7.451	7.451, 7.451	0.006, 0.006	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0042, 0.0030	0.0035, 0.0020
	MEDIAN	NA	7.451	7.451	0.006	0.003	0.006
	MIN, MAX	NA, NA	7.451, 7.451	7.451, 7.451	0.006, 0.006	0.000, 0.006	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.006	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	8.122, 5.249	8.565, 6.443	8.388, 5.936	0.024, NA	0.012, 0.010	0.017, NA
	SD, SE	6.6582, 1.5693	6.0448, 1.1633	6.2264, 0.9282	0.0597, 0.0113	0.0064, 0.0011	0.0407, 0.0052
	MEDIAN	7.174	7.094	7.168	0.009	0.011	0.011
	MIN, MAX	0.091, 29.379	0.840, 23.398	0.091, 29.379	0.000, 0.323	0.006, 0.028	0.000, 0.323
	5%, 95%	0.091, 29.379	1.561, 18.937	0.840, 18.937	0.000, 0.040	0.006, 0.023	0.006, 0.028
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.040, 0.040	0.040, 0.040
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.040	0.040
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.040, 0.040	0.040, 0.040
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	8.320, 6.316	8.320, 6.316	0.006, 0.006	NA, NA	0.006, 0.006
	SD, SE	NA, NA	7.7059, 4.4490	7.7059, 4.4490	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4.557	4.557	0.006	NA	0.006
	MIN, MAX	NA, NA	3.218, 17.184	3.218, 17.184	0.006, 0.006	NA, NA	0.006, 0.006
	5%, 95%	NA, NA	3.218, 17.184	3.218, 17.184	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	5.522, 5.522	5.522, 5.522	0.006, 0.006	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	5.522	5.522	0.006	0.006	0.006
	MIN, MAX	NA, NA	5.522, 5.522	5.522, 5.522	0.006, 0.006	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	7.819, 5.065	9.930, 7.762	9.075, 6.530	0.012, NA	0.012, 0.010	0.012, NA
	SD, SE	5.2007, 1.2614	7.0282, 1.4056	6.3694, 0.9828	0.0163, 0.0031	0.0062, 0.0011	0.0119, 0.0015
	MEDIAN	7.332	8.229	7.786	0.006	0.011	0.011
	MIN, MAX	0.034, 18.813	1.271, 29.431	0.034, 29.431	0.000, 0.079	0.006, 0.028	0.000, 0.079
	5%, 95%	0.034, 18.813	2.174, 22.728	2.174, 18.813	0.000, 0.051	0.006, 0.028	0.006, 0.028
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.051, 0.051	0.051, 0.051
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.051	0.051
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.051, 0.051	0.051, 0.051
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	11.136, 6.605	11.136, 6.605	0.011, 0.011	NA, NA	0.011, 0.011
	SD, SE	NA, NA	13.2241, 7.6349	13.2241, 7.6349	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4.784	4.784	0.011	NA	0.011
	MIN, MAX	NA, NA	2.287, 26.338	2.287, 26.338	0.011, 0.011	NA, NA	0.011, 0.011
	5%, 95%	NA, NA	2.287, 26.338	2.287, 26.338	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537643

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 64 of 7)

Lab: Harrogate
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	7.372, 7.372	7.372, 7.372	0.006, 0.006	0.004, 0.003	0.005, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0028, 0.0020	0.0023, 0.0013
	MEDIAN	NA	7.372	7.372	0.006	0.004	0.006
	MIN, MAX	NA, NA	7.372, 7.372	7.372, 7.372	0.006, 0.006	0.002, 0.006	0.002, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.002, 0.006	0.002, 0.006
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	8.016, 5.428	9.486, 7.135	8.911, 6.411	0.017, NA	0.012, 0.011	0.014, NA
	SD, SE	6.0188, 1.4186	6.4652, 1.2218	6.2683, 0.9242	0.0287, 0.0054	0.0060, 0.0010	0.0199, 0.0026
	MEDIAN	7.346	8.701	7.684	0.008	0.011	0.009
	MIN, MAX	0.089, 25.944	0.783, 25.568	0.089, 25.944	0.000, 0.149	0.006, 0.032	0.000, 0.149
	5%, 95%	0.089, 25.944	1.510, 22.053	1.510, 22.053	0.004, 0.051	0.006, 0.023	0.004, 0.038
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.036, 0.036	0.036, 0.036
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.036	0.036
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.036, 0.036	0.036, 0.036
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	9.856, 6.835	9.856, 6.835	0.008, 0.008	NA, NA	0.008, 0.008
	SD, SE	NA, NA	10.4295, 6.0215	10.4295, 6.0215	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4.226	4.226	0.008	NA	0.008
	MIN, MAX	NA, NA	3.452, 21.891	3.452, 21.891	0.008, 0.008	NA, NA	0.008, 0.008
	5%, 95%	NA, NA	3.452, 21.891	3.452, 21.891	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537644

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 65 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2831.870, 2831.870	2831.870, 2831.870	9.300, 9.300	1.712, 1.708	4.241, 3.005
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.1584, 0.1120	4.3824, 2.5302
	MEDIAN	NA	2831.870	2831.870	9.300	1.712	1.824
	MIN, MAX	NA, NA	2831.872, 2831.872	2831.872, 2831.872	9.300, 9.300	1.600, 1.824	1.600, 9.300
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.600, 1.824	1.600, 9.300
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	8481.670, 5058.790	7578.570, 5710.640	7931.960, 5446.120	13.068, 5.205	4.287, 3.014	8.318, 3.873
	SD, SE	7495.8000, 1766.7800	4855.6200, 917.6260	5964.1400, 879.3650	20.4281, 3.8605	4.9927, 0.8691	14.8509, 1.9015
	MEDIAN	7795.660	7518.910	7618.950	3.278	2.800	2.895
	MIN, MAX	80.370, 31233.615	185.625, 21231.840	80.370, 31233.615	0.950, 84.568	0.800, 25.920	0.800, 84.568
	5%, 95%	80.370, 31233.600	1264.620, 15362.600	795.900, 18631.300	1.030, 59.985	1.140, 14.950	1.140, 40.870
	BLQ Values Included	0	0	0	8	15	23
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	19.728, 19.728	19.728, 19.728
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	19.728	19.728
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	19.728, 19.728	19.728, 19.728
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	7951.470, 5125.600	7951.470, 5125.600	3.969, 3.969	NA, NA	3.969, 3.969
	SD, SE	NA, NA	8335.1500, 4812.3000	8335.1500, 4812.3000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4881.630	4881.630	3.969	NA	3.969
	MIN, MAX	NA, NA	1586.590, 17386.180	1586.590, 17386.180	3.969, 3.969	NA, NA	3.969, 3.969
	5%, 95%	NA, NA	1586.590, 17386.200	1586.590, 17386.200	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 66 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3881.020, 3881.020	3881.020, 3881.020	12.100, 12.100	2.204, 1.982	5.503, 3.622
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.3633, 0.9640	5.7942, 3.3453
	MEDIAN	NA	3881.020	3881.020	12.100	2.204	3.168
	MIN, MAX	NA, NA	3881.020, 3881.020	3881.020, 3881.020	12.100, 12.100	1.240, 3.168	1.240, 12.100
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.240, 3.168	1.240, 12.100
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	7771.090, 5070.700	9461.060, 7553.440	8785.070, 6440.420	19.230, 6.507	5.354, 3.607	11.723, 4.729
	SD, SE	5217.2100, 1229.7100	5337.5500, 1027.2100	5296.4300, 789.5450	38.0416, 7.1892	5.9671, 1.0387	26.8109, 3.4328
	MEDIAN	7298.240	8606.170	8283.720	3.392	2.795	2.910
	MIN, MAX	48.420, 20994.570	504.248, 22147.192	48.420, 22147.192	1.000, 191.422	1.050, 24.208	1.000, 191.422
	5%, 95%	48.420, 20994.600	1171.890, 19677.600	842.508, 19677.600	1.023, 74.670	1.280, 23.013	1.148, 43.240
	BLQ Values Included	0	0	0	2	13	15
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	19.500, 19.500	19.500, 19.500
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	19.500	19.500
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	19.500, 19.500	19.500, 19.500
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6900.420, 4134.040	6900.420, 4134.040	3.813, 3.813	NA, NA	3.813, 3.813
	SD, SE	NA, NA	8348.5100, 4820.0200	8348.5100, 4820.0200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2337.230	2337.230	3.813	NA	3.813
	MIN, MAX	NA, NA	1828.066, 16535.970	1828.066, 16535.970	3.813, 3.813	NA, NA	3.813, 3.813
	5%, 95%	NA, NA	1828.070, 16536.000	1828.070, 16536.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 67 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4432.200, 4432.200	4432.200, 4432.200	7.566, 7.566	2.994, 2.292	4.518, 3.413
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.7238, 1.9260	3.2676, 1.8865
	MEDIAN	NA	4432.200	4432.200	7.566	2.994	4.920
	MIN, MAX	NA, NA	4432.200, 4432.200	4432.200, 4432.200	7.566, 7.566	1.068, 4.920	1.068, 7.566
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.068, 4.920	1.068, 7.566
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	8564.710, 4903.590	9169.970, 7538.190	8924.980, 6333.980	12.749, 5.660	3.876, 3.035	7.949, 4.040
	SD, SE	7430.9800, 1802.2800	5314.5500, 1062.9100	6178.4100, 953.3500	20.8390, 3.9382	3.2769, 0.5704	14.8668, 1.9035
	MEDIAN	6563.700	8287.470	6833.960	3.665	2.870	3.200
	MIN, MAX	52.295, 27454.900	1308.324, 19074.831	52.295, 27454.900	1.430, 89.830	1.089, 14.840	1.089, 89.830
	5%, 95%	52.295, 27454.900	1721.870, 17880.000	1308.320, 18489.900	1.720, 55.313	1.300, 11.523	1.430, 44.835
	BLQ Values Included	0	0	0	7	18	25
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	21.688, 21.688	21.688, 21.688
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	21.688	21.688
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	21.688, 21.688	21.688, 21.688
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3656.420, 2657.260	3656.420, 2657.260	2.145, 2.145	NA, NA	2.145, 2.145
	SD, SE	NA, NA	3602.3900, 2079.8400	3602.3900, 2079.8400	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1912.150	1912.150	2.145	NA	2.145
	MIN, MAX	NA, NA	1258.180, 7798.934	1258.180, 7798.934	2.145, 2.145	NA, NA	2.145, 2.145
	5%, 95%	NA, NA	1258.180, 7798.930	1258.180, 7798.930	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 68 of 7)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3715.030, 3715.030	3715.030, 3715.030	9.655, 9.655	2.304, 2.075	4.754, 3.464
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.4149, 1.0005	4.3607, 2.5177
	MEDIAN	NA	3715.030	3715.030	9.655	2.304	3.304
	MIN, MAX	NA, NA	3715.030, 3715.030	3715.030, 3715.030	9.655, 9.655	1.303, 3.304	1.303, 9.655
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.303, 3.304	1.303, 9.655
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	8308.190, 5267.650	8471.750, 6874.230	8407.750, 6194.220	15.016, 6.537	4.506, 3.446	9.330, 4.624
	SD, SE	6258.3500, 1475.1100	4947.6500, 935.0190	5430.5100, 800.6860	22.9228, 4.3320	3.8151, 0.6641	16.4956, 2.1120
	MEDIAN	6721.080	7291.270	7035.320	5.076	2.833	3.190
	MIN, MAX	60.362, 23472.700	666.066, 20818.000	60.362, 23472.700	1.318, 97.065	1.067, 18.212	1.067, 97.065
	5%, 95%	60.362, 23472.700	1386.130, 16456.700	827.503, 20711.600	1.374, 66.991	1.355, 11.887	1.367, 42.982
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	20.305, 20.305	20.305, 20.305
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	20.305	20.305
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	20.305, 20.305	20.305, 20.305
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6169.430, 4039.830	6169.430, 4039.830	3.309, 3.309	NA, NA	3.309, 3.309
	SD, SE	NA, NA	6742.0000, 3892.5000	6742.0000, 3892.5000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3043.670	3043.670	3.309	NA	3.309
	MIN, MAX	NA, NA	1557.610, 13907.000	1557.610, 13907.000	3.309, 3.309	NA, NA	3.309, 3.309
	5%, 95%	NA, NA	1557.610, 13907.000	1557.610, 13907.000	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537648

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 69 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	14734.200, 14734.200	14734.200, 14734.200	48.388, 48.388	8.908, 8.888	22.068, 15.636
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.8238, 0.5825	22.8015, 13.1645
	MEDIAN	NA	14734.200	14734.200	48.388	8.908	9.490
	MIN, MAX	NA, NA	14734.230, 14734.230	14734.230, 14734.230	48.388, 48.388	8.325, 9.490	8.325, 48.388
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	8.325, 9.490	8.325, 48.388
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	44130.100, 26320.900	39431.300, 29712.400	41270.000, 28336.100	67.994, 27.082	22.304, 15.682	43.276, 20.152
	SD, SE	39000.6000, 9192.5400	25263.8000, 4774.4100	31031.4000, 4575.3400	106.2870, 20.0864	25.9771, 4.5220	77.2694, 9.8933
	MEDIAN	40560.800	39120.900	39641.400	17.056	14.568	15.063
	MIN, MAX	418.165, 162508.499	965.807, 110469.264	418.165, 162508.499	4.943, 440.007	4.162, 134.862	4.162, 440.007
	5%, 95%	418.165, 162508.000	6579.820, 79931.400	4141.070, 96938.400	5.359, 312.102	5.931, 77.785	5.931, 212.647
	BLQ Values Included	0	0	0	8	15	23
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	102.645, 102.645	102.645, 102.645
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	102.645	102.645
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	102.645, 102.645	102.645, 102.645
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	41371.500, 26668.500	41371.500, 26668.500	20.651, 20.651	NA, NA	20.651, 20.651
	SD, SE	NA, NA	43367.8000, 25038.4000	43367.8000, 25038.4000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	25399.100	25399.100	20.651	NA	20.651
	MIN, MAX	NA, NA	8255.028, 90460.295	8255.028, 90460.295	20.651, 20.651	NA, NA	20.651, 20.651
	5%, 95%	NA, NA	8255.030, 90460.300	8255.030, 90460.300	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 70 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	20192.900, 20192.900	20192.900, 20192.900	62.956, 62.956	11.468, 10.313	28.630, 18.848
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	7.0930, 5.0155	30.1470, 17.4054
	MEDIAN	NA	20192.900	20192.900	62.956	11.468	16.483
	MIN, MAX	NA, NA	20192.947, 20192.947	20192.947, 20192.947	62.956, 62.956	6.452, 16.483	6.452, 62.956
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.452, 16.483	6.452, 62.956
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	40433.000, 26382.900	49225.900, 39300.500	45708.700, 33509.500	100.055, 33.856	27.857, 18.766	60.997, 24.604
	SD, SE	27145.1000, 6398.1700	27771.2000, 5344.5800	27557.3000, 4108.0000	197.9310, 37.4054	31.0468, 5.4046	139.4970, 17.8608
	MEDIAN	37972.700	44777.900	43100.200	17.649	14.542	15.141
	MIN, MAX	251.929, 109234.748	2623.602, 115231.840	251.929, 115231.840	5.203, 995.969	5.463, 125.954	5.203, 995.969
	5%, 95%	251.929, 109235.000	6097.320, 102382.000	4383.570, 102382.000	5.323, 388.508	6.660, 119.737	5.973, 224.978
	BLQ Values Included	0	0	0	2	13	15
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	101.459, 101.459	101.459, 101.459
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	101.459	101.459
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	101.459, 101.459	101.459, 101.459
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	35902.900, 21509.400	35902.900, 21509.400	19.839, 19.839	NA, NA	19.839, 19.839
	SD, SE	NA, NA	43437.3000, 25078.5000	43437.3000, 25078.5000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	12160.600	12160.600	19.839	NA	19.839
	MIN, MAX	NA, NA	9511.427, 86036.652	9511.427, 86036.652	19.839, 19.839	NA, NA	19.839, 19.839
	5%, 95%	NA, NA	9511.430, 86036.700	9511.430, 86036.700	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	23060.700, 23060.700	23060.700, 23060.700	39.366, 39.366	15.578, 11.927	23.507, 17.758
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	14.1718, 10.0210	17.0013, 9.8157
	MEDIAN	NA	23060.700	23060.700	39.366	15.578	25.599
	MIN, MAX	NA, NA	23060.737, 23060.737	23060.737, 23060.737	39.366, 39.366	5.557, 25.599	5.557, 39.366
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.557, 25.599	5.557, 39.366
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	44562.200, 25513.400	47711.300, 39221.200	46436.700, 32955.700	66.333, 29.451	20.166, 15.789	41.357, 21.020
	SD, SE	38663.4000, 9377.2500	27651.6000, 5530.3200	32146.3000, 4960.2800	108.4250, 20.4904	17.0496, 2.9679	77.3519, 9.9039
	MEDIAN	34150.900	43119.700	35557.100	19.069	14.933	16.650
	MIN, MAX	272.091, 142847.845	6807.210, 99246.346	272.091, 142847.845	7.440, 467.385	5.666, 77.213	5.666, 467.385
	5%, 95%	272.091, 142848.000	8958.900, 93029.900	6807.210, 96202.800	8.949, 287.794	6.764, 59.954	7.440, 233.277
	BLQ Values Included	0	0	0	7	18	25
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	112.843, 112.843	112.843, 112.843
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	112.843	112.843
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	112.843, 112.843	112.843, 112.843
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	19024.400, 13825.700	19024.400, 13825.700	11.160, 11.160	NA, NA	11.160, 11.160
	SD, SE	NA, NA	18743.2000, 10821.4000	18743.2000, 10821.4000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	9948.930	9948.930	11.160	NA	11.160
	MIN, MAX	NA, NA	6546.311, 40577.854	6546.311, 40577.854	11.160, 11.160	NA, NA	11.160, 11.160
	5%, 95%	NA, NA	6546.310, 40577.900	6546.310, 40577.900	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	19329.300, 19329.300	19329.300, 19329.300	50.237, 50.237	11.985, 10.794	24.735, 18.022
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	7.3631, 5.2065	22.6905, 13.1004
	MEDIAN	NA	19329.300	19329.300	50.237	11.985	17.191
	MIN, MAX	NA, NA	19329.300, 19329.300	19329.300, 19329.300	50.237, 50.237	6.778, 17.191	6.778, 50.237
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.778, 17.191	6.778, 50.237
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	43227.600, 27407.600	44078.500, 35766.600	43745.500, 32228.500	78.127, 34.013	23.442, 17.932	48.543, 24.057
	SD, SE	32562.3000, 7675.0200	25742.6000, 4864.9000	28255.0000, 4165.9800	119.2670, 22.5393	19.8504, 3.4555	85.8264, 10.9889
	MEDIAN	34969.800	37936.500	36604.800	26.410	14.742	16.599
	MIN, MAX	314.062, 122129.000	3465.540, 108316.000	314.062, 122129.000	6.859, 505.029	5.550, 94.757	5.550, 505.029
	5%, 95%	314.062, 122129.000	7212.010, 85624.400	4305.500, 107763.000	7.151, 348.552	7.048, 61.850	7.111, 223.634
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	105.649, 105.649	105.649, 105.649
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	105.649	105.649
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	105.649, 105.649	105.649, 105.649
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	32099.600, 21019.300	32099.600, 21019.300	17.217, 17.217	NA, NA	17.217, 17.217
	SD, SE	NA, NA	35078.8000, 20252.7000	35078.8000, 20252.7000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	15836.200	15836.200	17.217	NA	17.217
	MIN, MAX	NA, NA	8104.260, 72358.300	8104.260, 72358.300	17.217, 17.217	NA, NA	17.217, 17.217
	5%, 95%	NA, NA	8104.260, 72358.300	8104.260, 72358.300	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.936, 1.936	1.936, 1.936	0.004, 0.004	0.001, 0.001	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0017, 0.0010
	MEDIAN	NA	1.936	1.936	0.004	0.001	0.001
	MIN, MAX	NA, NA	1.936, 1.936	1.936, 1.936	0.004, 0.004	0.001, 0.001	0.001, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.004
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5.847, 3.827	7.149, 5.138	6.639, 4.579	0.008, NA	0.004, 0.003	0.006, NA
	SD, SE	4.1160, 0.9701	5.0330, 0.9512	4.6916, 0.6917	0.0126, 0.0024	0.0063, 0.0011	0.0098, 0.0013
	MEDIAN	5.353	5.705	5.517	0.002	0.002	0.002
	MIN, MAX	0.076, 15.997	0.154, 18.383	0.076, 18.383	0.000, 0.052	0.001, 0.037	0.000, 0.052
	5%, 95%	0.076, 15.997	0.676, 18.231	0.370, 15.997	0.001, 0.042	0.001, 0.011	0.001, 0.021
	BLQ Values Included	0	0	0	8	15	23
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.022, 0.022	0.022, 0.022
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.022	0.022
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.022, 0.022	0.022, 0.022
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5.041, 3.622	5.041, 3.622	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	4.8423, 2.7957	4.8423, 2.7957	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.147	3.147	0.004	NA	0.004
	MIN, MAX	NA, NA	1.432, 10.544	1.432, 10.544	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	1.432, 10.544	1.432, 10.544	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.656, 2.656	2.656, 2.656	0.005, 0.005	0.002, 0.001	0.003, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0021, 0.0012
	MEDIAN	NA	2.656	2.656	0.005	0.002	0.002
	MIN, MAX	NA, NA	2.656, 2.656	2.656, 2.656	0.005, 0.005	0.001, 0.002	0.001, 0.005
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.002	0.001, 0.005
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	5.688, 3.726	7.815, 5.954	6.964, 4.936	0.012, NA	0.004, 0.003	0.008, NA
	SD, SE	4.0901, 0.9640	5.3627, 1.0321	4.9566, 0.7389	0.0224, 0.0042	0.0047, 0.0008	0.0159, 0.0020
	MEDIAN	4.759	6.121	5.662	0.003	0.002	0.002
	MIN, MAX	0.054, 15.619	0.503, 20.024	0.054, 20.024	0.000, 0.099	0.001, 0.021	0.000, 0.099
	5%, 95%	0.054, 15.619	0.918, 18.908	0.503, 18.134	0.001, 0.071	0.001, 0.020	0.001, 0.026
	BLQ Values Included	0	0	0	2	13	15
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.027, 0.027	0.027, 0.027
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.027	0.027
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.027, 0.027	0.027, 0.027
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5.268, 3.684	5.268, 3.684	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	5.4003, 3.1179	5.4003, 3.1179	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.757	2.757	0.004	NA	0.004
	MIN, MAX	NA, NA	1.581, 11.467	1.581, 11.467	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	1.581, 11.467	1.581, 11.467	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.669, 2.669	2.669, 2.669	0.003, 0.003	0.003, 0.002	0.003, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0021, 0.0015	0.0015, 0.0009
	MEDIAN	NA	2.669	2.669	0.003	0.003	0.003
	MIN, MAX	NA, NA	2.669, 2.669	2.669, 2.669	0.003, 0.003	0.001, 0.004	0.001, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.004	0.001, 0.004
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	5.880, 3.539	7.951, 6.206	7.113, 4.944	0.007, 0.003	0.003, 0.003	0.005, 0.003
	SD, SE	4.7052, 1.1412	5.6132, 1.1226	5.3049, 0.8186	0.0107, 0.0020	0.0026, 0.0004	0.0076, 0.0010
	MEDIAN	5.037	5.598	5.084	0.002	0.002	0.002
	MIN, MAX	0.046, 17.626	1.148, 23.294	0.046, 23.294	0.001, 0.050	0.001, 0.010	0.001, 0.050
	5%, 95%	0.046, 17.626	1.303, 17.524	1.148, 17.524	0.001, 0.026	0.001, 0.009	0.001, 0.019
	BLQ Values Included	0	0	0	7	18	25
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.029, 0.029	0.029, 0.029
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.029	0.029
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.029, 0.029	0.029, 0.029
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5.706, 3.414	5.706, 3.414	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	6.9022, 3.9850	6.9022, 3.9850	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.966	1.966	0.002	NA	0.002
	MIN, MAX	NA, NA	1.481, 13.671	1.481, 13.671	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	1.481, 13.671	1.481, 13.671	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.420, 2.420	2.420, 2.420	0.004, 0.004	0.002, 0.001	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0015, 0.0009
	MEDIAN	NA	2.420	2.420	0.004	0.002	0.002
	MIN, MAX	NA, NA	2.420, 2.420	2.420, 2.420	0.004, 0.004	0.001, 0.002	0.001, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.002	0.001, 0.004
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5.814, 3.797	7.554, 5.870	6.873, 4.950	0.009, 0.004	0.004, 0.003	0.006, 0.003
	SD, SE	4.1774, 0.9846	5.1249, 0.9685	4.8051, 0.7085	0.0129, 0.0024	0.0037, 0.0007	0.0094, 0.0012
	MEDIAN	4.913	5.816	5.417	0.003	0.003	0.003
	MIN, MAX	0.059, 16.414	0.653, 20.195	0.059, 20.195	0.001, 0.046	0.001, 0.021	0.001, 0.046
	5%, 95%	0.059, 16.414	0.914, 17.186	0.653, 16.414	0.001, 0.039	0.001, 0.009	0.001, 0.022
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.026, 0.026	0.026, 0.026
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.026	0.026
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.026, 0.026	0.026, 0.026
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5.338, 3.602	5.338, 3.602	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	5.7052, 3.2939	5.7052, 3.2939	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.623	2.623	0.003	NA	0.003
	MIN, MAX	NA, NA	1.498, 11.894	1.498, 11.894	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	1.498, 11.894	1.498, 11.894	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.073, 10.073	10.073, 10.073	0.021, 0.021	0.005, 0.005	0.010, 0.008
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0092, 0.0053
	MEDIAN	NA	10.073	10.073	0.021	0.005	0.005
	MIN, MAX	NA, NA	10.073, 10.073	10.073, 10.073	0.021, 0.021	0.005, 0.005	0.005, 0.021
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.005	0.005, 0.021
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	30.420, 19.913	37.195, 26.732	34.544, 23.822	0.040, NA	0.021, 0.014	0.030, NA
	SD, SE	21.4154, 5.0476	26.1869, 4.9489	24.4107, 3.5992	0.0659, 0.0124	0.0329, 0.0057	0.0513, 0.0066
	MEDIAN	27.849	29.683	28.702	0.010	0.010	0.010
	MIN, MAX	0.395, 83.232	0.801, 95.647	0.395, 95.647	0.000, 0.271	0.005, 0.193	0.000, 0.271
	5%, 95%	0.395, 83.232	3.517, 94.856	1.925, 83.232	0.005, 0.219	0.005, 0.057	0.005, 0.109
	BLQ Values Included	0	0	0	8	15	23
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.114, 0.114	0.114, 0.114
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.114	0.114
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.114, 0.114	0.114, 0.114
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	26.228, 18.846	26.228, 18.846	0.021, 0.021	NA, NA	0.021, 0.021
	SD, SE	NA, NA	25.1939, 14.5457	25.1939, 14.5457	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	16.374	16.374	0.021	NA	0.021
	MIN, MAX	NA, NA	7.451, 54.860	7.451, 54.860	0.021, 0.021	NA, NA	0.021, 0.021
	5%, 95%	NA, NA	7.451, 54.860	7.451, 54.860	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13.819, 13.819	13.819, 13.819	0.026, 0.026	0.008, 0.007	0.014, 0.011
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0035, 0.0025	0.0110, 0.0063
	MEDIAN	NA	13.819	13.819	0.026	0.008	0.010
	MIN, MAX	NA, NA	13.819, 13.819	13.819, 13.819	0.026, 0.026	0.005, 0.010	0.005, 0.026
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.010	0.005, 0.026
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	29.593, 19.388	40.659, 30.980	36.233, 25.684	0.061, NA	0.022, 0.015	0.040, NA
	SD, SE	21.2809, 5.0160	27.9021, 5.3698	25.7890, 3.8444	0.1164, 0.0220	0.0246, 0.0043	0.0825, 0.0106
	MEDIAN	24.761	31.848	29.459	0.016	0.010	0.010
	MIN, MAX	0.281, 81.266	2.617, 104.185	0.281, 104.185	0.000, 0.515	0.005, 0.109	0.000, 0.515
	5%, 95%	0.281, 81.266	4.776, 98.378	2.617, 94.351	0.005, 0.369	0.005, 0.104	0.005, 0.135
	BLQ Values Included	0	0	0	2	13	15
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.140, 0.140	0.140, 0.140
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.140	0.140
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.140, 0.140	0.140, 0.140
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	27.411, 19.166	27.411, 19.166	0.021, 0.021	NA, NA	0.021, 0.021
	SD, SE	NA, NA	28.0978, 16.2223	28.0978, 16.2223	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	14.345	14.345	0.021	NA	0.021
	MIN, MAX	NA, NA	8.226, 59.663	8.226, 59.663	0.021, 0.021	NA, NA	0.021, 0.021
	5%, 95%	NA, NA	8.226, 59.663	8.226, 59.663	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13.887, 13.887	13.887, 13.887	0.016, 0.016	0.013, 0.010	0.014, 0.012
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0113, 0.0080	0.0082, 0.0047
	MEDIAN	NA	13.887	13.887	0.016	0.013	0.016
	MIN, MAX	NA, NA	13.887, 13.887	13.887, 13.887	0.016, 0.016	0.005, 0.021	0.005, 0.021
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.021	0.005, 0.021
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	30.593, 18.410	41.370, 32.292	37.008, 25.723	0.034, 0.016	0.018, 0.014	0.025, 0.015
	SD, SE	24.4813, 5.9376	29.2056, 5.8411	27.6017, 4.2590	0.0558, 0.0105	0.0135, 0.0024	0.0395, 0.0051
	MEDIAN	26.208	29.126	26.453	0.010	0.010	0.010
	MIN, MAX	0.239, 91.708	5.973, 121.199	0.239, 121.199	0.005, 0.260	0.005, 0.052	0.005, 0.260
	5%, 95%	0.239, 91.708	6.780, 91.177	5.973, 91.177	0.005, 0.135	0.005, 0.047	0.005, 0.099
	BLQ Values Included	0	0	0	7	18	25
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.151, 0.151	0.151, 0.151
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.151	0.151
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.151, 0.151	0.151, 0.151
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	29.688, 17.765	29.688, 17.765	0.010, 0.010	NA, NA	0.010, 0.010
	SD, SE	NA, NA	35.9117, 20.7336	35.9117, 20.7336	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	10.229	10.229	0.010	NA	0.010
	MIN, MAX	NA, NA	7.706, 71.130	7.706, 71.130	0.010, 0.010	NA, NA	0.010, 0.010
	5%, 95%	NA, NA	7.706, 71.130	7.706, 71.130	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12.593, 12.593	12.593, 12.593	0.021, 0.021	0.009, 0.008	0.013, 0.011
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0049, 0.0035	0.0080, 0.0046
	MEDIAN	NA	12.593	12.593	0.021	0.009	0.012
	MIN, MAX	NA, NA	12.593, 12.593	12.593, 12.593	0.021, 0.021	0.005, 0.012	0.005, 0.021
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.012	0.005, 0.021
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	30.249, 19.747	39.304, 30.544	35.761, 25.752	0.045, 0.020	0.020, 0.015	0.032, 0.017
	SD, SE	21.7351, 5.1230	26.6646, 5.0391	25.0006, 3.6861	0.0672, 0.0127	0.0197, 0.0034	0.0490, 0.0063
	MEDIAN	25.563	30.259	28.180	0.015	0.016	0.016
	MIN, MAX	0.305, 85.402	3.399, 105.075	0.305, 105.075	0.003, 0.241	0.005, 0.111	0.003, 0.241
	5%, 95%	0.305, 85.402	4.755, 89.417	3.399, 85.402	0.005, 0.203	0.005, 0.047	0.005, 0.116
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.135, 0.135	0.135, 0.135
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.135	0.135
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.135, 0.135	0.135, 0.135
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	27.776, 18.742	27.776, 18.742	0.017, 0.017	NA, NA	0.017, 0.017
	SD, SE	NA, NA	29.6834, 17.1377	29.6834, 17.1377	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	13.649	13.649	0.017	NA	0.017
	MIN, MAX	NA, NA	7.794, 61.884	7.794, 61.884	0.017, 0.017	NA, NA	0.017, 0.017
	5%, 95%	NA, NA	7.794, 61.884	7.794, 61.884	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3047.040, 3047.040	3047.040, 3047.040	7.800, 7.800	1.228, 1.170	3.418, 2.202
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.5268, 0.3725	3.8129, 2.2014
	MEDIAN	NA	3047.040	3047.040	7.800	1.228	1.600
	MIN, MAX	NA, NA	3047.040, 3047.040	3047.040, 3047.040	7.800, 7.800	0.855, 1.600	0.855, 7.800
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.855, 1.600	0.855, 7.800
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5856.480, 3547.470	5650.290, 4255.870	5730.970, 3963.220	10.657, 4.631	3.875, 2.807	6.988, 3.532
	SD, SE	4830.8700, 1138.6500	3809.5000, 719.9270	4187.3700, 617.3930	16.2646, 3.0737	4.5882, 0.7987	11.9114, 1.5251
	MEDIAN	5526.840	5539.210	5539.210	2.954	2.725	2.725
	MIN, MAX	42.441, 20367.215	143.550, 18150.580	42.441, 20367.215	0.950, 67.936	0.880, 25.488	0.880, 67.936
	5%, 95%	42.441, 20367.200	935.760, 11844.000	645.000, 11844.000	1.030, 46.035	1.140, 11.700	1.140, 30.820
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	13.974, 13.974	13.974, 13.974
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	13.974	13.974
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	13.974, 13.974	13.974, 13.974
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6866.590, 4111.280	6866.590, 4111.280	3.564, 3.564	NA, NA	3.564, 3.564
	SD, SE	NA, NA	7808.3700, 4508.1700	7808.3700, 4508.1700	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3597.140	3597.140	3.564	NA	3.564
	MIN, MAX	NA, NA	1224.380, 15778.245	1224.380, 15778.245	3.564, 3.564	NA, NA	3.564, 3.564
	5%, 95%	NA, NA	1224.380, 15778.200	1224.380, 15778.200	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2733.160, 2733.160	2733.160, 2733.160	6.050, 6.050	2.105, 1.919	3.420, 2.814
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.2233, 0.8650	2.4364, 1.4066
	MEDIAN	NA	2733.160	2733.160	6.050	2.105	2.970
	MIN, MAX	NA, NA	2733.159, 2733.159	2733.159, 2733.159	6.050, 6.050	1.240, 2.970	1.240, 6.050
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.240, 2.970	1.240, 6.050
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	5893.470, 3777.180	7343.350, 5814.770	6763.400, 4893.130	15.523, 5.591	4.303, 3.206	9.453, 4.139
	SD, SE	3983.1000, 938.8260	4210.2500, 810.2640	4137.6700, 616.8070	30.2584, 5.7183	4.1293, 0.7188	21.2810, 2.7248
	MEDIAN	5281.350	7237.740	6389.210	3.269	2.740	2.900
	MIN, MAX	24.210, 16978.770	400.405, 18154.368	24.210, 18154.368	0.875, 152.550	0.750, 20.909	0.750, 152.550
	5%, 95%	24.210, 16978.800	884.631, 15032.800	722.866, 15032.800	0.902, 60.135	1.248, 12.282	1.023, 31.960
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	13.650, 13.650	13.650, 13.650
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	13.650	13.650
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	13.650, 13.650	13.650, 13.650
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5697.380, 3287.460	5697.380, 3287.460	3.660, 3.660	NA, NA	3.660, 3.660
	SD, SE	NA, NA	7095.6900, 4096.7000	7095.6900, 4096.7000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1671.690	1671.690	3.660	NA	3.660
	MIN, MAX	NA, NA	1530.080, 13890.360	1530.080, 13890.360	3.660, 3.660	NA, NA	3.660, 3.660
	5%, 95%	NA, NA	1530.080, 13890.400	1530.080, 13890.400	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3277.960, 3277.960	3277.960, 3277.960	5.820, 5.820	1.559, 1.480	2.979, 2.336
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.6944, 0.4910	2.5086, 1.4483
	MEDIAN	NA	3277.960	3277.960	5.820	1.559	2.050
	MIN, MAX	NA, NA	3277.959, 3277.959	3277.959, 3277.959	5.820, 5.820	1.068, 2.050	1.068, 5.820
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.068, 2.050	1.068, 5.820
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	6143.550, 3478.250	6668.110, 5516.600	6455.780, 4577.130	10.156, 4.957	3.461, 2.832	6.534, 3.662
	SD, SE	4990.3900, 1210.3500	3768.8500, 753.7700	4254.5500, 656.4910	16.1095, 3.0444	2.5591, 0.4455	11.4713, 1.4687
	MEDIAN	4755.720	5789.160	5126.680	2.971	2.760	2.898
	MIN, MAX	21.379, 15121.480	976.686, 13569.448	21.379, 15121.480	1.430, 72.800	0.990, 10.528	0.990, 72.800
	5%, 95%	21.379, 15121.500	1154.780, 13029.400	976.686, 14222.600	1.720, 38.750	1.260, 9.805	1.430, 31.610
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	16.830, 16.830	16.830, 16.830
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	16.830	16.830
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	16.830, 16.830	16.830, 16.830
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3146.700, 2296.410	3146.700, 2296.410	1.859, 1.859	NA, NA	1.859, 1.859
	SD, SE	NA, NA	3132.6800, 1808.6500	3132.6800, 1808.6500	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1338.390	1338.390	1.859	NA	1.859
	MIN, MAX	NA, NA	1337.700, 6764.008	1337.700, 6764.008	1.859, 1.859	NA, NA	1.859, 1.859
	5%, 95%	NA, NA	1337.700, 6764.010	1337.700, 6764.010	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3019.390, 3019.390	3019.390, 3019.390	6.557, 6.557	1.631, 1.597	3.273, 2.558
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4632, 0.3275	2.8631, 1.6530
	MEDIAN	NA	3019.390	3019.390	6.557	1.631	1.958
	MIN, MAX	NA, NA	3019.390, 3019.390	3019.390, 3019.390	6.557, 6.557	1.303, 1.958	1.303, 6.557
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.303, 1.958	1.303, 6.557
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5997.370, 3797.210	6357.490, 5145.690	6216.580, 4568.770	12.112, 5.643	3.880, 3.166	7.659, 4.128
	SD, SE	4284.2000, 1009.8000	3721.7400, 703.3430	3908.4900, 576.2750	18.2553, 3.4499	2.7955, 0.4866	13.0860, 1.6755
	MEDIAN	5057.480	5683.440	5453.020	4.401	2.833	3.182
	MIN, MAX	29.343, 17222.200	506.880, 16339.400	29.343, 17222.200	1.277, 76.940	1.038, 13.701	1.038, 76.940
	5%, 95%	29.343, 17222.200	991.725, 12433.200	696.229, 12433.200	1.374, 56.114	1.276, 8.975	1.369, 33.167
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	14.818, 14.818	14.818, 14.818
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	14.818	14.818
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	14.818, 14.818	14.818, 14.818
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5236.890, 3316.650	5236.890, 3316.650	3.028, 3.028	NA, NA	3.028, 3.028
	SD, SE	NA, NA	5996.5800, 3462.1300	5996.5800, 3462.1300	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2202.410	2202.410	3.028	NA	3.028
	MIN, MAX	NA, NA	1364.050, 12144.200	1364.050, 12144.200	3.028, 3.028	NA, NA	3.028, 3.028
	5%, 95%	NA, NA	1364.050, 12144.200	1364.050, 12144.200	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537664

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 85 of ?)

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	15853.700, 15853.700	15853.700, 15853.700	40.583, 40.583	6.387, 6.086	17.786, 11.455
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.7407, 1.9380	19.8380, 11.4535
	MEDIAN	NA	15853.700	15853.700	40.583	6.387	8.325
	MIN, MAX	NA, NA	15853.749, 15853.749	15853.749, 15853.749	40.583, 40.583	4.449, 8.325	4.449, 40.583
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	4.449, 8.325	4.449, 40.583
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	30471.300, 18457.500	29398.500, 22143.300	29818.300, 20620.600	55.450, 24.093	20.163, 14.605	36.360, 18.377
	SD, SE	25135.0000, 5924.3800	19820.8000, 3745.7800	21786.9000, 3212.3000	84.6248, 15.9926	23.8725, 4.1557	61.9751, 7.9351
	MEDIAN	28756.100	28820.500	28820.500	15.367	14.178	14.178
	MIN, MAX	220.821, 105970.620	746.891, 94437.468	220.821, 105970.620	4.943, 353.471	4.579, 132.614	4.579, 353.471
	5%, 95%	220.821, 105971.000	4868.760, 61624.300	3355.940, 61624.300	5.359, 239.520	5.931, 60.875	5.931, 160.356
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	72.707, 72.707	72.707, 72.707
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	72.707	72.707
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	72.707, 72.707	72.707, 72.707
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	35726.900, 21391.000	35726.900, 21391.000	18.543, 18.543	NA, NA	18.543, 18.543
	SD, SE	NA, NA	40627.0000, 23456.0000	40627.0000, 23456.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	18715.900	18715.900	18.543	NA	18.543
	MIN, MAX	NA, NA	6370.449, 82094.209	6370.449, 82094.209	18.543, 18.543	NA, NA	18.543, 18.543
	5%, 95%	NA, NA	6370.450, 82094.200	6370.450, 82094.200	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	14220.600, 14220.600	14220.600, 14220.600	31.478, 31.478	10.953, 9.985	17.794, 14.641
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	6.3647, 4.5005	12.6762, 7.3186
	MEDIAN	NA	14220.600	14220.600	31.478	10.953	15.453
	MIN, MAX	NA, NA	14220.626, 14220.626	14220.626, 14220.626	31.478, 31.478	6.452, 15.453	6.452, 31.478
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.452, 15.453	6.452, 31.478
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	30663.700, 19652.700	38207.500, 30254.200	35190.000, 25459.000	80.764, 29.088	22.388, 16.683	49.183, 21.533
	SD, SE	20724.1000, 4884.7100	21906.0000, 4215.8000	21528.3000, 3209.2500	157.4340, 29.7523	21.4850, 3.7401	110.7250, 14.1769
	MEDIAN	27478.800	37658.000	33243.100	17.009	14.256	15.089
	MIN, MAX	125.965, 88340.540	2083.307, 94457.177	125.965, 94457.177	4.553, 793.718	3.902, 108.790	3.902, 793.718
	5%, 95%	125.965, 88340.500	4602.740, 78215.800	3761.070, 78215.800	4.693, 312.882	6.493, 63.903	5.323, 166.288
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	71.021, 71.021	71.021, 71.021
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	71.021	71.021
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	71.021, 71.021	71.021, 71.021
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	29643.400, 17104.700	29643.400, 17104.700	19.043, 19.043	NA, NA	19.043, 19.043
	SD, SE	NA, NA	36918.9000, 21315.1000	36918.9000, 21315.1000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	8697.790	8697.790	19.043	NA	19.043
	MIN, MAX	NA, NA	7961.006, 72271.543	7961.006, 72271.543	19.043, 19.043	NA, NA	19.043, 19.043
	5%, 95%	NA, NA	7961.010, 72271.500	7961.010, 72271.500	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17055.200, 17055.200	17055.200, 17055.200	30.281, 30.281	8.112, 7.699	15.501, 12.153
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	3.6126, 2.5545	13.0520, 7.5356
	MEDIAN	NA	17055.200	17055.200	30.281	8.112	10.666
	MIN, MAX	NA, NA	17055.221, 17055.221	17055.221, 17055.221	30.281, 30.281	5.557, 10.666	5.557, 30.281
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.557, 10.666	5.557, 30.281
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	31964.900, 18097.300	34694.200, 28702.800	33589.400, 23814.800	52.843, 25.791	18.009, 14.736	33.999, 19.053
	SD, SE	25965.0000, 6297.4300	19609.3000, 3921.8700	22136.4000, 3415.7200	83.8175, 15.8400	13.3148, 2.3178	59.6851, 7.6419
	MEDIAN	24744.000	30121.000	26674.100	15.459	14.360	15.078
	MIN, MAX	111.235, 78677.060	5081.697, 70601.838	111.235, 78677.060	7.440, 378.778	5.151, 54.777	5.151, 378.778
	5%, 95%	111.235, 78677.100	6008.340, 67792.100	5081.700, 74000.000	8.949, 201.616	6.556, 51.015	7.440, 164.467
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	87.566, 87.566	87.566, 87.566
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	87.566	87.566
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	87.566, 87.566	87.566, 87.566
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	16372.300, 11948.200	16372.300, 11948.200	9.672, 9.672	NA, NA	9.672, 9.672
	SD, SE	NA, NA	16299.3000, 9410.4300	16299.3000, 9410.4300	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	6963.650	6963.650	9.672	NA	9.672
	MIN, MAX	NA, NA	6960.053, 35193.134	6960.053, 35193.134	9.672, 9.672	NA, NA	9.672, 9.672
	5%, 95%	NA, NA	6960.050, 35193.100	6960.050, 35193.100	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	15709.900, 15709.900	15709.900, 15709.900	34.114, 34.114	8.484, 8.310	17.027, 13.306
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.4119, 1.7055	14.8957, 8.6001
	MEDIAN	NA	15709.900	15709.900	34.114	8.484	10.189
	MIN, MAX	NA, NA	15709.900, 15709.900	15709.900, 15709.900	34.114, 34.114	6.778, 10.189	6.778, 34.114
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.778, 10.189	6.778, 34.114
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	31204.300, 19756.900	33078.100, 26773.000	32344.900, 23771.300	63.019, 29.361	20.186, 16.475	39.847, 21.479
	SD, SE	22290.7000, 5253.9700	19364.2000, 3659.5000	20335.9000, 2998.3600	94.9825, 17.9500	14.5447, 2.5319	68.0864, 8.7176
	MEDIAN	26314.100	29571.000	28372.100	22.896	14.742	16.556
	MIN, MAX	152.674, 89607.000	2637.300, 85014.100	152.674, 89607.000	6.643, 400.319	5.402, 71.284	5.402, 400.319
	5%, 95%	152.674, 89607.000	5159.950, 64690.100	3622.480, 64690.100	7.151, 291.961	6.639, 46.695	7.125, 172.570
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	77.098, 77.098	77.098, 77.098
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	77.098	77.098
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	77.098, 77.098	77.098, 77.098
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	27247.500, 17256.500	27247.500, 17256.500	15.753, 15.753	NA, NA	15.753, 15.753
	SD, SE	NA, NA	31200.2000, 18013.5000	31200.2000, 18013.5000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	11459.100	11459.100	15.753	NA	15.753
	MIN, MAX	NA, NA	7097.170, 63186.300	7097.170, 63186.300	15.753, 15.753	NA, NA	15.753, 15.753
	5%, 95%	NA, NA	7097.170, 63186.300	7097.170, 63186.300	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537668

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.083, 2.083	2.083, 2.083	0.003, 0.003	0.001, 0.001	0.002, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0012, 0.0007
	MEDIAN	NA	2.083	2.083	0.003	0.001	0.001
	MIN, MAX	NA, NA	2.083, 2.083	2.083, 2.083	0.003, 0.003	0.001, 0.001	0.001, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.003
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4.056, 2.684	5.365, 3.829	4.853, 3.332	0.006, NA	0.004, 0.003	0.005, NA
	SD, SE	2.5920, 0.6109	3.8727, 0.7319	3.4574, 0.5098	0.0100, 0.0019	0.0060, 0.0011	0.0081, 0.0010
	MEDIAN	4.045	4.520	4.322	0.002	0.002	0.002
	MIN, MAX	0.040, 8.886	0.119, 14.351	0.040, 14.351	0.000, 0.042	0.001, 0.036	0.000, 0.042
	5%, 95%	0.040, 8.886	0.500, 13.466	0.300, 12.478	0.001, 0.032	0.001, 0.008	0.001, 0.019
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.016, 0.016	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.016	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.016, 0.016	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.331, 2.905	4.331, 2.905	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	4.5767, 2.6423	4.5767, 2.6423	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.319	2.319	0.003	NA	0.003
	MIN, MAX	NA, NA	1.105, 9.569	1.105, 9.569	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	1.105, 9.569	1.105, 9.569	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 90 of ?)

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.870, 1.870	1.870, 1.870	0.003, 0.003	0.002, 0.001	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0010, 0.0006
	MEDIAN	NA	1.870	1.870	0.003	0.002	0.002
	MIN, MAX	NA, NA	1.870, 1.870	1.870, 1.870	0.003, 0.003	0.001, 0.002	0.001, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.002	0.001, 0.003
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	4.195, 2.776	6.035, 4.584	5.299, 3.750	0.010, NA	0.004, 0.003	0.006, NA
	SD, SE	2.6525, 0.6252	4.0714, 0.7835	3.6529, 0.5445	0.0178, 0.0034	0.0033, 0.0006	0.0126, 0.0016
	MEDIAN	3.834	4.990	4.201	0.002	0.002	0.002
	MIN, MAX	0.027, 10.012	0.400, 15.297	0.027, 15.297	0.000, 0.079	0.001, 0.018	0.000, 0.079
	5%, 95%	0.027, 10.012	0.693, 14.865	0.400, 12.899	0.001, 0.057	0.001, 0.010	0.001, 0.019
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.019, 0.019	0.019, 0.019
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.019	0.019
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.019, 0.019	0.019, 0.019
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.309, 2.929	4.309, 2.929	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	4.6213, 2.6681	4.6213, 2.6681	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.972	1.972	0.004	NA	0.004
	MIN, MAX	NA, NA	1.323, 9.632	1.323, 9.632	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	1.323, 9.632	1.323, 9.632	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 91 of ?)

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.974, 1.974	1.974, 1.974	0.003, 0.003	0.001, 0.001	0.002, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0012, 0.0007
	MEDIAN	NA	1.974	1.974	0.003	0.001	0.001
	MIN, MAX	NA, NA	1.974, 1.974	1.974, 1.974	0.003, 0.003	0.001, 0.001	0.001, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.003
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	4.141, 2.512	5.775, 4.542	5.114, 3.574	0.005, 0.003	0.003, 0.003	0.004, 0.003
	SD, SE	2.9060, 0.7048	3.8840, 0.7768	3.5757, 0.5517	0.0085, 0.0016	0.0022, 0.0004	0.0060, 0.0008
	MEDIAN	3.299	4.235	3.940	0.002	0.002	0.002
	MIN, MAX	0.019, 9.708	0.770, 15.542	0.019, 15.542	0.001, 0.041	0.001, 0.008	0.001, 0.041
	5%, 95%	0.019, 9.708	0.972, 11.642	0.770, 11.609	0.001, 0.018	0.001, 0.008	0.001, 0.014
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.022, 0.022	0.022, 0.022
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.022	0.022
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.022, 0.022	0.022, 0.022
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.936, 2.950	4.936, 2.950	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	5.9949, 3.4611	5.9949, 3.4611	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.574	1.574	0.002	NA	0.002
	MIN, MAX	NA, NA	1.376, 11.857	1.376, 11.857	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	1.376, 11.857	1.376, 11.857	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.976, 1.976	1.976, 1.976	0.003, 0.003	0.001, 0.001	0.002, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0012, 0.0007
	MEDIAN	NA	1.976	1.976	0.003	0.001	0.001
	MIN, MAX	NA, NA	1.976, 1.976	1.976, 1.976	0.003, 0.003	0.001, 0.001	0.001, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.001, 0.001	0.001, 0.003
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4.143, 2.740	5.657, 4.400	5.065, 3.656	0.007, 0.003	0.003, 0.003	0.005, 0.003
	SD, SE	2.6080, 0.6147	3.7620, 0.7110	3.4087, 0.5026	0.0103, 0.0019	0.0030, 0.0005	0.0075, 0.0010
	MEDIAN	3.555	4.522	4.265	0.002	0.003	0.002
	MIN, MAX	0.029, 9.245	0.497, 14.264	0.029, 14.264	0.001, 0.037	0.001, 0.017	0.001, 0.037
	5%, 95%	0.029, 9.245	0.654, 12.984	0.497, 12.705	0.001, 0.033	0.001, 0.008	0.001, 0.017
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.019, 0.019	0.019, 0.019
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.019	0.019
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.019, 0.019	0.019, 0.019
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.525, 2.966	4.525, 2.966	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	5.0545, 2.9182	5.0545, 2.9182	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.889	1.889	0.003	NA	0.003
	MIN, MAX	NA, NA	1.334, 10.353	1.334, 10.353	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	1.334, 10.353	1.334, 10.353	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.838, 10.838	10.838, 10.838	0.016, 0.016	0.005, 0.005	0.009, 0.007
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0064, 0.0037
	MEDIAN	NA	10.838	10.838	0.016	0.005	0.005
	MIN, MAX	NA, NA	10.838, 10.838	10.838, 10.838	0.016, 0.016	0.005, 0.005	0.005, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.005	0.005, 0.016
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	21.104, 13.962	27.912, 19.922	25.248, 17.335	0.033, NA	0.019, 0.013	0.025, NA
	SD, SE	13.4863, 3.1788	20.1498, 3.8080	17.9891, 2.6523	0.0521, 0.0099	0.0314, 0.0055	0.0424, 0.0054
	MEDIAN	21.044	23.515	22.488	0.010	0.010	0.010
	MIN, MAX	0.208, 46.234	0.619, 74.668	0.208, 74.668	0.000, 0.219	0.005, 0.187	0.000, 0.219
	5%, 95%	0.208, 46.234	2.602, 70.064	1.561, 64.923	0.005, 0.166	0.005, 0.042	0.005, 0.099
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.083, 0.083	0.083, 0.083
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.083	0.083
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.083, 0.083	0.083, 0.083
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	22.534, 15.116	22.534, 15.116	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	23.8128, 13.7483	23.8128, 13.7483	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	12.066	12.066	0.016	NA	0.016
	MIN, MAX	NA, NA	5.749, 49.788	5.749, 49.788	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	5.749, 49.788	5.749, 49.788	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	9.730, 9.730	9.730, 9.730	0.016, 0.016	0.008, 0.007	0.010, 0.009
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0035, 0.0025	0.0055, 0.0032
	MEDIAN	NA	9.730	9.730	0.016	0.008	0.010
	MIN, MAX	NA, NA	9.730, 9.730	9.730, 9.730	0.016, 0.016	0.005, 0.010	0.005, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.010	0.005, 0.016
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	21.828, 14.439	31.398, 23.851	27.570, 19.512	0.049, NA	0.018, 0.014	0.032, NA
	SD, SE	13.8009, 3.2529	21.1836, 4.0768	19.0062, 2.8333	0.0927, 0.0175	0.0174, 0.0030	0.0654, 0.0084
	MEDIAN	19.946	25.963	21.858	0.010	0.010	0.010
	MIN, MAX	0.140, 52.092	2.081, 79.590	0.140, 79.590	0.000, 0.411	0.005, 0.094	0.000, 0.411
	5%, 95%	0.140, 52.092	3.606, 77.343	2.081, 67.113	0.005, 0.297	0.005, 0.052	0.005, 0.099
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.099, 0.099	0.099, 0.099
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.099	0.099
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.099, 0.099	0.099, 0.099
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	22.420, 15.240	22.420, 15.240	0.021, 0.021	NA, NA	0.021, 0.021
	SD, SE	NA, NA	24.0442, 13.8819	24.0442, 13.8819	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	10.260	10.260	0.021	NA	0.021
	MIN, MAX	NA, NA	6.884, 50.115	6.884, 50.115	0.021, 0.021	NA, NA	0.021, 0.021
	5%, 95%	NA, NA	6.884, 50.115	6.884, 50.115	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.271, 10.271	10.271, 10.271	0.016, 0.016	0.005, 0.005	0.009, 0.007
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0064, 0.0037
	MEDIAN	NA	10.271	10.271	0.016	0.005	0.005
	MIN, MAX	NA, NA	10.271, 10.271	10.271, 10.271	0.016, 0.016	0.005, 0.005	0.005, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.005	0.005, 0.016
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	21.545, 13.070	30.049, 23.631	26.607, 18.594	0.027, 0.013	0.016, 0.013	0.021, 0.013
	SD, SE	15.1200, 3.6671	20.2085, 4.0417	18.6042, 2.8707	0.0441, 0.0083	0.0114, 0.0020	0.0312, 0.0040
	MEDIAN	17.165	22.035	20.497	0.010	0.010	0.010
	MIN, MAX	0.099, 50.511	4.006, 80.865	0.099, 80.865	0.005, 0.213	0.005, 0.042	0.005, 0.213
	5%, 95%	0.099, 50.511	5.057, 60.573	4.006, 60.402	0.005, 0.094	0.005, 0.042	0.005, 0.073
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.114, 0.114	0.114, 0.114
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.114	0.114
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.114, 0.114	0.114, 0.114
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	25.680, 15.350	25.680, 15.350	0.010, 0.010	NA, NA	0.010, 0.010
	SD, SE	NA, NA	31.1913, 18.0083	31.1913, 18.0083	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	8.190	8.190	0.010	NA	0.010
	MIN, MAX	NA, NA	7.159, 61.692	7.159, 61.692	0.010, 0.010	NA, NA	0.010, 0.010
	5%, 95%	NA, NA	7.159, 61.692	7.159, 61.692	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.280, 10.280	10.280, 10.280	0.016, 0.016	0.006, 0.006	0.009, 0.008
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0014, 0.0010	0.0059, 0.0034
	MEDIAN	NA	10.280	10.280	0.016	0.006	0.007
	MIN, MAX	NA, NA	10.280, 10.280	10.280, 10.280	0.016, 0.016	0.005, 0.007	0.005, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.005, 0.007	0.005, 0.016
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	21.558, 14.243	29.434, 22.895	26.352, 19.015	0.036, 0.017	0.018, 0.014	0.026, 0.015
	SD, SE	13.5702, 3.1985	19.5739, 3.6991	17.7357, 2.6150	0.0537, 0.0102	0.0154, 0.0027	0.0389, 0.0050
	MEDIAN	18.494	23.528	22.189	0.012	0.014	0.012
	MIN, MAX	0.149, 48.103	2.586, 74.215	0.149, 74.215	0.003, 0.194	0.005, 0.088	0.003, 0.194
	5%, 95%	0.149, 48.103	3.405, 67.557	2.586, 66.106	0.003, 0.170	0.005, 0.040	0.005, 0.088
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.099, 0.099	0.099, 0.099
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.099	0.099
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.099, 0.099	0.099, 0.099
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	23.545, 15.431	23.545, 15.431	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	26.2978, 15.1831	26.2978, 15.1831	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	9.828	9.828	0.016	NA	0.016
	MIN, MAX	NA, NA	6.941, 53.865	6.941, 53.865	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	6.941, 53.865	6.941, 53.865	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	2	3
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	7.800, 7.800	2.508, NA	4.272, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	3.5468, 2.5080	3.9529, 2.2822
	MEDIAN	NA	NA	NA	7.800	2.508	5.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	7.800, 7.800	0.000, 5.016	0.000, 7.800
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 5.016	0.000, 7.800
	BLQ Values Included	NA	NA	NA	0	1	1
Caucasian	N	18	28	46	23	26	49
	MEAN, GEO MEAN	13658.800, 7347.440	10032.800, 6934.350	11451.700, 7093.150	15.522, NA	3.434, NA	9.108, NA
	SD, SE	14825.2000, 3494.3200	6849.4200, 1294.4200	10694.9000, 1576.8700	23.9229, 4.9883	4.9697, 0.9746	17.6727, 2.5247
	MEDIAN	8980.790	8936.480	8936.480	5.640	1.155	1.930
	MIN, MAX	197.400, 56537.828	218.900, 26230.442	197.400, 56537.828	0.000, 86.504	0.000, 16.900	0.000, 86.504
	5%, 95%	197.400, 56537.800	757.770, 25398.700	757.770, 26230.400	0.000, 72.540	0.000, 14.949	0.000, 52.260
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	30.003, 30.003	30.003, 30.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	30.003	30.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	30.003, 30.003	30.003, 30.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5644.650, 4723.350	5644.650, 4723.350	2.106, 2.106	NA, NA	2.106, 2.106
	SD, SE	NA, NA	3363.1600, 1941.7200	3363.1600, 1941.7200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	6683.240	6683.240	2.106	NA	2.106
	MIN, MAX	NA, NA	1884.710, 8366.015	1884.710, 8366.015	2.106, 2.106	NA, NA	2.106, 2.106
	5%, 95%	NA, NA	1884.710, 8366.020	1884.710, 8366.020	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-6
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	5972.250, 5972.250	5972.250, 5972.250	31.350, 31.350	0.528, NA	10.802, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.7467, 0.5280	17.8029, 10.2785
	MEDIAN	NA	5972.250	5972.250	31.350	0.528	1.056
	MIN, MAX	NA, NA	5972.252, 5972.252	5972.252, 5972.252	31.350, 31.350	0.000, 1.056	0.000, 31.350
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 1.056	0.000, 31.350
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	25	30	55
	MEAN, GEO MEAN	9769.280, 6028.730	11018.400, 8622.860	10518.800, 7472.760	22.042, NA	6.394, NA	13.506, NA
	SD, SE	8845.0300, 2084.7900	6783.7000, 1305.5200	7602.8100, 1133.3600	43.0455, 8.6091	13.0209, 2.3773	31.2474, 4.2134
	MEDIAN	7733.960	9640.240	9075.580	3.198	1.226	1.575
	MIN, MAX	126.000, 38811.750	540.383, 26263.300	126.000, 38811.750	0.000, 202.270	0.000, 62.122	0.000, 202.270
	5%, 95%	126.000, 38811.800	1494.590, 24231.800	622.537, 24231.800	0.000, 75.525	0.000, 31.536	0.000, 62.122
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	30.420, 30.420	30.420, 30.420
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	30.420	30.420
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	30.420, 30.420	30.420, 30.420
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6259.460, 4196.480	6259.460, 4196.480	0.763, 0.763	NA, NA	0.763, 0.763
	SD, SE	NA, NA	6570.0600, 3793.2300	6570.0600, 3793.2300	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3462.880	3462.880	0.763	NA	0.763
	MIN, MAX	NA, NA	1550.374, 13765.125	1550.374, 13765.125	0.763, 0.763	NA, NA	0.763, 0.763
	5%, 95%	NA, NA	1550.370, 13765.100	1550.370, 13765.100	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	6005.500, 6005.500	6005.500, 6005.500	9.021, 9.021	7.483, NA	7.995, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	10.5819, 7.4825	7.5350, 4.3504
	MEDIAN	NA	6005.500	6005.500	9.021	7.483	9.021
	MIN, MAX	NA, NA	6005.498, 6005.498	6005.498, 6005.498	9.021, 9.021	0.000, 14.965	0.000, 14.965
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 14.965	0.000, 14.965
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	26	31	57
	MEAN, GEO MEAN	12597.300, 6606.370	13017.200, 10104.900	12847.200, 8507.940	14.592, NA	2.553, NA	8.045, NA
	SD, SE	14948.0000, 3625.4200	8966.1300, 1793.2300	11588.7000, 1788.1800	26.5888, 5.2145	5.4800, 0.9842	19.1911, 2.5419
	MEDIAN	8891.740	11237.700	9149.350	3.172	0.000	0.940
	MIN, MAX	160.868, 64170.700	1725.522, 33098.780	160.868, 64170.700	0.000, 88.660	0.000, 26.235	0.000, 88.660
	5%, 95%	160.868, 64170.700	2950.620, 31402.400	1725.520, 31402.400	0.000, 86.250	0.000, 12.480	0.000, 71.050
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	25.331, 25.331	25.331, 25.331
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	25.331	25.331
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	25.331, 25.331	25.331, 25.331
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	2	2	1	0	1
	MEAN, GEO MEAN	NA, NA	4185.030, 4009.390	4185.030, 4009.390	1.430, 1.430	NA, NA	1.430, 1.430
	SD, SE	NA, NA	1696.6600, 1199.7200	1696.6600, 1199.7200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4185.030	4185.030	1.430	NA	1.430
	MIN, MAX	NA, NA	2985.312, 5384.756	2985.312, 5384.756	1.430, 1.430	NA, NA	1.430, 1.430
	5%, 95%	NA, NA	2985.310, 5384.760	2985.310, 5384.760	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	5988.880, 5988.880	5988.880, 5988.880	16.057, 16.057	3.506, NA	7.690, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.9582, 3.5060	8.0499, 4.6476
	MEDIAN	NA	5988.880	5988.880	16.057	3.506	7.012
	MIN, MAX	NA, NA	5988.880, 5988.880	5988.880, 5988.880	16.057, 16.057	0.000, 7.012	0.000, 16.057
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 7.012	0.000, 16.057
Caucasian	N	18	28	46	28	32	60
	MEAN, GEO MEAN	12023.200, 7040.190	11000.400, 8755.380	11400.700, 8039.380	16.659, NA	3.856, NA	9.830, NA
	SD, SE	11899.5000, 2804.7400	6866.4600, 1297.6400	9057.3900, 1335.4400	27.0061, 5.1037	5.9000, 1.0430	19.8379, 2.5611
	MEDIAN	8821.500	9418.540	9418.540	4.403	1.173	2.314
	MIN, MAX	161.423, 49042.900	828.268, 27011.000	161.423, 49042.900	0.000, 104.787	0.000, 23.501	0.000, 104.787
	5%, 95%	161.423, 49042.900	2052.100, 23927.100	828.268, 27011.000	0.000, 87.582	0.000, 19.257	0.000, 50.471
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.585, 28.585	28.585, 28.585
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.585	28.585
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.585, 28.585	28.585, 28.585
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5088.880, 4100.660	5088.880, 4100.660	1.433, 1.433	NA, NA	1.433, 1.433
	SD, SE	NA, NA	3777.8400, 2181.1400	3777.8400, 2181.1400	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4377.140	4377.140	1.433	NA	1.433
	MIN, MAX	NA, NA	1717.540, 9171.970	1717.540, 9171.970	1.433, 1.433	NA, NA	1.433, 1.433
	5%, 95%	NA, NA	1717.540, 9171.970	1717.540, 9171.970	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	2	3
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.002, NA	0.002, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0021, 0.0015	0.0017, 0.0010
	MEDIAN	NA	NA	NA	0.003	0.002	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.000, 0.003	0.000, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.003	0.000, 0.003
	BLQ Values Included	NA	NA	NA	0	1	1
Caucasian	N	18	28	46	23	26	49
	MEAN, GEO MEAN	9.316, 5.558	9.283, 6.239	9.296, 5.963	0.009, NA	0.003, NA	0.006, NA
	SD, SE	8.9395, 2.1071	7.1439, 1.3501	7.7981, 1.1498	0.0151, 0.0031	0.0040, 0.0008	0.0111, 0.0016
	MEDIAN	7.365	7.431	7.378	0.002	0.001	0.001
	MIN, MAX	0.186, 37.904	0.182, 24.795	0.182, 37.904	0.000, 0.053	0.000, 0.015	0.000, 0.053
	5%, 95%	0.186, 37.904	0.724, 24.215	0.365, 24.215	0.000, 0.051	0.000, 0.012	0.000, 0.025
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.034, 0.034	0.034, 0.034
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.034	0.034
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.034, 0.034	0.034, 0.034
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.695, 3.338	3.695, 3.338	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	1.7684, 1.0210	1.7684, 1.0210	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4.309	4.309	0.002	NA	0.002
	MIN, MAX	NA, NA	1.701, 5.074	1.701, 5.074	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	1.701, 5.074	1.701, 5.074	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4.086, 4.086	4.086, 4.086	0.014, 0.014	0.001, NA	0.005, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0078, 0.0045
	MEDIAN	NA	4.086	4.086	0.014	0.001	0.001
	MIN, MAX	NA, NA	4.086, 4.086	4.086, 4.086	0.014, 0.014	0.000, 0.001	0.000, 0.014
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.014
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	25	30	55
	MEAN, GEO MEAN	7.764, 4.431	9.261, 6.797	8.663, 5.728	0.013, NA	0.005, NA	0.009, NA
	SD, SE	8.8779, 2.0925	7.3950, 1.4232	7.9572, 1.1862	0.0253, 0.0051	0.0102, 0.0019	0.0189, 0.0026
	MEDIAN	4.949	7.035	6.309	0.002	0.001	0.001
	MIN, MAX	0.141, 37.773	0.539, 31.266	0.141, 37.773	0.000, 0.105	0.000, 0.053	0.000, 0.105
	5%, 95%	0.141, 37.773	1.171, 24.592	0.539, 24.592	0.000, 0.072	0.000, 0.016	0.000, 0.053
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.041, 0.041	0.041, 0.041
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.041	0.041
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.041, 0.041	0.041, 0.041
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.990, 3.739	4.990, 3.739	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	4.1764, 2.4112	4.1764, 2.4112	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4.084	4.084	0.001	NA	0.001
	MIN, MAX	NA, NA	1.341, 9.545	1.341, 9.545	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	1.341, 9.545	1.341, 9.545	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 103 of 7)

Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.616, 3.616	3.616, 3.616	0.004, 0.004	0.006, NA	0.005, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0078, 0.0055	0.0056, 0.0032
	MEDIAN	NA	3.616	3.616	0.004	0.006	0.004
	MIN, MAX	NA, NA	3.616, 3.616	3.616, 3.616	0.004, 0.004	0.000, 0.011	0.000, 0.011
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.011	0.000, 0.011
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	26	31	57
	MEAN, GEO MEAN	9.048, 4.767	11.321, 8.320	10.401, 6.641	0.007, NA	0.002, NA	0.004, NA
	SD, SE	10.5051, 2.5479	9.6795, 1.9359	9.9592, 1.5367	0.0132, 0.0026	0.0043, 0.0008	0.0097, 0.0013
	MEDIAN	6.526	7.591	6.861	0.002	0.000	0.000
	MIN, MAX	0.141, 41.198	1.718, 40.332	0.141, 41.198	0.000, 0.050	0.000, 0.018	0.000, 0.050
	5%, 95%	0.141, 41.198	1.968, 30.778	1.718, 30.778	0.000, 0.040	0.000, 0.012	0.000, 0.030
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.034, 0.034	0.034, 0.034
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.034	0.034
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.034, 0.034	0.034, 0.034
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	2	2	1	0	1
	MEAN, GEO MEAN	NA, NA	6.255, 5.383	6.255, 5.383	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	4.5036, 3.1845	4.5036, 3.1845	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	6.255	6.255	0.002	NA	0.002
	MIN, MAX	NA, NA	3.070, 9.439	3.070, 9.439	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	3.070, 9.439	3.070, 9.439	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.851, 3.851	3.851, 3.851	0.007, 0.007	0.003, NA	0.004, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0035, 0.0025	0.0036, 0.0021
	MEDIAN	NA	3.851	3.851	0.007	0.003	0.005
	MIN, MAX	NA, NA	3.851, 3.851	3.851, 3.851	0.007, 0.007	0.000, 0.005	0.000, 0.007
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.005	0.000, 0.007
Caucasian	N	18	28	46	28	32	60
	MEAN, GEO MEAN	8.691, 5.073	9.869, 7.427	9.408, 6.398	0.010, NA	0.003, NA	0.006, NA
	SD, SE	9.1846, 2.1648	7.4965, 1.4167	8.1194, 1.1971	0.0152, 0.0029	0.0047, 0.0008	0.0113, 0.0015
	MEDIAN	5.838	7.341	6.767	0.002	0.001	0.002
	MIN, MAX	0.156, 38.958	0.813, 30.859	0.156, 38.958	0.000, 0.052	0.000, 0.021	0.000, 0.052
	5%, 95%	0.156, 38.958	1.351, 26.074	0.813, 26.074	0.000, 0.049	0.000, 0.011	0.000, 0.034
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.036, 0.036	0.036, 0.036
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.036	0.036
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.036, 0.036	0.036, 0.036
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.454, 3.599	4.454, 3.599	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	3.2949, 1.9023	3.2949, 1.9023	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.821	3.821	0.002	NA	0.002
	MIN, MAX	NA, NA	1.521, 8.019	1.521, 8.019	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	1.521, 8.019	1.521, 8.019	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 105 of ?)

Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	2	3
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.6, 2.6	4.4, NA	3.8, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	6.22, 4.40	4.52, 2.61
	MEDIAN	NA	NA	NA	2.6	4.4	2.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.6, 2.6	0.0, 8.8	0.0, 8.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 8.8	0.0, 8.8
	BLQ Values Included	NA	NA	NA	0	1	1
Caucasian	N	18	28	46	23	26	49
	MEAN, GEO MEAN	8694.8, 4489.1	6171.7, 4011.8	7159.0, 4192.2	10.2, NA	1.8, NA	5.8, NA
	SD, SE	11055.20, 2605.73	4733.83, 894.61	7820.89, 1153.13	20.51, 4.28	2.52, 0.49	14.64, 2.09
	MEDIAN	5531.3	5316.7	5421.3	4.2	1.0	1.6
	MIN, MAX	140.0, 48117.3	79.6, 16292.2	79.6, 48117.3	0.0, 98.3	0.0, 9.9	0.0, 98.3
	5%, 95%	140.0, 48117.3	814.8, 14940.4	811.1, 16292.2	0.0, 26.0	0.0, 6.2	0.0, 17.7
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	21.9, 21.9	21.9, 21.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	21.9	21.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	21.9, 21.9	21.9, 21.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2860.1, 2156.0	2860.1, 2156.0	2.6, 2.6	NA, NA	2.6, 2.6
	SD, SE	NA, NA	1991.68, 1149.90	1991.68, 1149.90	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3414.7	3414.7	2.6	NA	2.6
	MIN, MAX	NA, NA	649.9, 4515.7	649.9, 4515.7	2.6, 2.6	NA, NA	2.6, 2.6
	5%, 95%	NA, NA	649.9, 4515.7	649.9, 4515.7	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537685

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4176.4, 4176.4	4176.4, 4176.4	11.4, 11.4	0.8, NA	4.3, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.13, 0.80	6.17, 3.56
	MEDIAN	NA	4176.4	4176.4	11.4	0.8	1.6
	MIN, MAX	NA, NA	4176.4, 4176.4	4176.4, 4176.4	11.4, 11.4	0.0, 1.6	0.0, 11.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 1.6	0.0, 11.4
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	25	30	55
	MEAN, GEO MEAN	6920.4, 4258.9	6984.6, 5247.6	6958.9, 4827.2	15.7, NA	3.3, NA	9.0, NA
	SD, SE	5859.62, 1381.13	4821.33, 927.86	5196.41, 774.63	36.97, 7.39	6.86, 1.25	25.92, 3.49
	MEDIAN	5673.1	5722.3	5722.3	1.6	0.5	1.6
	MIN, MAX	140.0, 23215.8	296.1, 18931.1	140.0, 23215.8	0.0, 179.0	0.0, 34.9	0.0, 179.0
	5%, 95%	140.0, 23215.8	1235.2, 15749.0	596.3, 15749.0	0.0, 62.4	0.0, 14.6	0.0, 38.0
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	15.6, 15.6	15.6, 15.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	15.6	15.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	15.6, 15.6	15.6, 15.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3849.5, 2668.2	3849.5, 2668.2	0.5, 0.5	NA, NA	0.5, 0.5
	SD, SE	NA, NA	3928.47, 2268.11	3928.47, 2268.11	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2144.2	2144.2	0.5	NA	0.5
	MIN, MAX	NA, NA	1061.9, 8342.5	1061.9, 8342.5	0.5, 0.5	NA, NA	0.5, 0.5
	5%, 95%	NA, NA	1061.9, 8342.5	1061.9, 8342.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537686

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 107 of 7)

Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4498.5, 4498.5	4498.5, 4498.5	3.1, 3.1	3.7, NA	3.5, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	5.16, 3.65	3.66, 2.12
	MEDIAN	NA	4498.5	4498.5	3.1	3.7	3.1
	MIN, MAX	NA, NA	4498.5, 4498.5	4498.5, 4498.5	3.1, 3.1	0.0, 7.3	0.0, 7.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 7.3	0.0, 7.3
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	26	31	57
	MEAN, GEO MEAN	7528.7, 3907.3	7906.7, 5515.1	7753.7, 4797.0	8.0, NA	1.4, NA	4.4, NA
	SD, SE	8771.50, 2127.40	8149.26, 1629.85	8302.70, 1281.13	14.82, 2.91	2.52, 0.45	10.61, 1.41
	MEDIAN	5225.9	5334.1	5280.0	2.1	0.0	0.5
	MIN, MAX	153.5, 29731.5	927.7, 40612.0	153.5, 40612.0	0.0, 68.2	0.0, 9.9	0.0, 68.2
	5%, 95%	153.5, 29731.5	1603.6, 16665.7	927.7, 29168.5	0.0, 27.6	0.0, 6.2	0.0, 25.0
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	14.6, 14.6	14.6, 14.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	14.6	14.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	14.6, 14.6	14.6, 14.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	2	2	1	0	1
	MEAN, GEO MEAN	NA, NA	4320.4, 4219.5	4320.4, 4219.5	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1312.32, 927.95	1312.32, 927.95	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4320.4	4320.4	1.0	NA	1.0
	MIN, MAX	NA, NA	3392.4, 5248.3	3392.4, 5248.3	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	3392.4, 5248.3	3392.4, 5248.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4337.5, 4337.5	4337.5, 4337.5	5.7, 5.7	3.0, NA	3.9, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.17, 2.95	3.35, 1.93
	MEDIAN	NA	4337.5	4337.5	5.7	3.0	5.7
	MIN, MAX	NA, NA	4337.5, 4337.5	4337.5, 4337.5	5.7, 5.7	0.0, 5.9	0.0, 5.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 5.9	0.0, 5.9
Caucasian	N	18	28	46	28	32	60
	MEAN, GEO MEAN	7766.0, 4760.1	6825.1, 5130.2	7193.3, 4982.1	11.2, NA	2.1, NA	6.3, NA
	SD, SE	6698.46, 1578.84	5036.47, 951.80	5690.85, 839.07	20.05, 3.79	3.06, 0.54	14.49, 1.87
	MEDIAN	6527.5	5337.8	5838.2	4.0	0.9	1.6
	MIN, MAX	144.5, 25999.9	434.5, 22446.3	144.5, 25999.9	0.0, 83.3	0.0, 13.2	0.0, 83.3
	5%, 95%	144.5, 25999.9	1217.9, 14963.3	640.7, 19989.6	0.0, 71.1	0.0, 8.2	0.0, 25.2
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	17.4, 17.4	17.4, 17.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	17.4	17.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	17.4, 17.4	17.4, 17.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3291.7, 2533.3	3291.7, 2533.3	1.4, 1.4	NA, NA	1.4, 1.4
	SD, SE	NA, NA	2406.84, 1389.59	2406.84, 1389.59	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3350.8	3350.8	1.4	NA	1.4
	MIN, MAX	NA, NA	855.9, 5668.5	855.9, 5668.5	1.4, 1.4	NA, NA	1.4, 1.4
	5%, 95%	NA, NA	855.9, 5668.5	855.9, 5668.5	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 109 of ?)

Lab: Madison
Biomarker: Total NNAL (pg/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	867456.000, 867456.000	867456.000, 867456.000	21000.000, 21000.000	6510.000, 5729.920	11340.000, 8834.300
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4369.9200, 3090.0000	8918.2300, 5148.9400
	MEDIAN	NA	867456.000	867456.000	21000.000	6510.000	9600.000
	MIN, MAX	NA, NA	867456.000, 867456.000	867456.000, 867456.000	21000.000, 21000.000	3420.000, 9600.000	3420.000, 21000.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3420.000, 9600.000	3420.000, 21000.000
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	28	45	28	33	61
	MEAN, GEO MEAN	803983.000, 509040.000	910243.000, 656327.000	870100.000, 596246.000	18119.100, 11087.100	12054.400, 11187.500	14838.200, 11141.300
	SD, SE	609148.0000, 147740.0000	617208.0000, 116641.0000	609433.0000, 90848.8000	33237.3000, 6281.2700	4600.3500, 800.8180	22753.0000, 2913.2200
	MEDIAN	529126.000	801427.000	785030.000	8940.000	11400.000	10800.000
	MIN, MAX	8460.000, 2084332.500	34650.000, 2307613.000	8460.000, 2307613.000	3180.000, 181986.000	4800.000, 20100.000	3180.000, 181986.000
	5%, 95%	8460.000, 2084330.000	37125.000, 2245880.000	37125.000, 2084330.000	3900.000, 41624.000	5760.000, 19500.000	4800.000, 20100.000
	BLQ Values Included	1	0	1	23	32	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8220.000, 8220.000	8220.000, 8220.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8220.000	8220.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8220.000, 8220.000	8220.000, 8220.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	718402.000, 390153.000	718402.000, 390153.000	4860.000, 4860.000	NA, NA	4860.000, 4860.000
	SD, SE	NA, NA	910491.0000, 525672.0000	910491.0000, 525672.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	257520.000	257520.000	4860.000	NA	4860.000
	MIN, MAX	NA, NA	130500.000, 1767185.000	130500.000, 1767185.000	4860.000, 4860.000	NA, NA	4860.000, 4860.000
	5%, 95%	NA, NA	130500.000, 1767190.000	130500.000, 1767190.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537689

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 110 of ?)

Lab: Madison
Biomarker: Total NNAL (pg/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	928092.000, 928092.000	928092.000, 928092.000	17460.000, 17460.000	9354.000, 8877.970	12056.000, 11123.100
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4166.2700, 2946.0000	5530.0400, 3192.7700
	MEDIAN	NA	928092.000	928092.000	17460.000	9354.000	12300.000
	MIN, MAX	NA, NA	928092.000, 928092.000	928092.000, 928092.000	17460.000, 17460.000	6408.000, 12300.000	6408.000, 17460.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6408.000, 12300.000	6408.000, 17460.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	780889.000, 484578.000	1074110.000, 822903.000	955423.000, 664140.000	13786.600, 11516.400	15466.400, 13442.400	14695.400, 12521.300
	SD, SE	625370.0000, 151675.0000	770160.0000, 154032.0000	721836.0000, 111382.0000	10971.7000, 2073.4500	10512.0000, 1829.9000	10668.5000, 1365.9600
	MEDIAN	540730.000	949130.000	823895.000	10740.000	12300.000	12000.000
	MIN, MAX	6288.000, 2075948.000	56730.000, 4046406.000	6288.000, 4046406.000	4500.000, 61490.000	5940.000, 53066.000	4500.000, 61490.000
	5%, 95%	6288.000, 2075950.000	97520.000, 1962480.000	97520.000, 1964160.000	4500.000, 28208.000	7200.000, 50799.000	6432.000, 28440.000
	BLQ Values Included	1	0	1	24	30	54
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10410.000, 10410.000	10410.000, 10410.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10410.000	10410.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10410.000, 10410.000	10410.000, 10410.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	336397.000, 251270.000	336397.000, 251270.000	8580.000, 8580.000	NA, NA	8580.000, 8580.000
	SD, SE	NA, NA	322408.0000, 186142.0000	322408.0000, 186142.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	166040.000	166040.000	8580.000	NA	8580.000
	MIN, MAX	NA, NA	134904.000, 708247.800	134904.000, 708247.800	8580.000, 8580.000	NA, NA	8580.000, 8580.000
	5%, 95%	NA, NA	134904.000, 708248.000	134904.000, 708248.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537690

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Total NNAL (pg/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	897774.000, 897774.000	897774.000, 897774.000	19230.000, 19230.000	7932.000, 7931.670	11698.000, 10655.400
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	101.8230, 72.0000	6523.3000, 3766.2300
	MEDIAN	NA	897774.000	897774.000	19230.000	7932.000	8004.000
	MIN, MAX	NA, NA	897774.000, 897774.000	897774.000, 897774.000	19230.000, 19230.000	7860.000, 8004.000	7860.000, 19230.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	7860.000, 8004.000	7860.000, 19230.000
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	803960.000, 518626.000	956030.000, 724433.000	896525.000, 635628.000	15952.900, 11794.800	13760.400, 12590.600	14766.800, 12218.800
	SD, SE	602619.0000, 142039.0000	597503.0000, 112917.0000	597517.0000, 88099.1000	18495.2000, 3495.2600	6357.8600, 1106.7600	13293.0000, 1702.0000
	MEDIAN	619904.000	855140.000	839770.000	9780.000	12660.000	11244.000
	MIN, MAX	7374.000, 2080140.000	46927.500, 2468210.000	7374.000, 2468210.000	3840.000, 97218.000	6400.000, 33874.500	3840.000, 97218.000
	5%, 95%	7374.000, 2080140.000	66085.000, 2135050.000	66085.000, 2080140.000	4590.000, 51557.000	6450.000, 30583.000	6400.000, 30583.000
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	9315.000, 9315.000	9315.000, 9315.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	9315.000	9315.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	9315.000, 9315.000	9315.000, 9315.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	527401.000, 330218.000	527401.000, 330218.000	6720.000, 6720.000	NA, NA	6720.000, 6720.000
	SD, SE	NA, NA	615621.0000, 355429.0000	615621.0000, 355429.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	196212.000	196212.000	6720.000	NA	6720.000
	MIN, MAX	NA, NA	148270.000, 1237720.000	148270.000, 1237720.000	6720.000, 6720.000	NA, NA	6720.000, 6720.000
	5%, 95%	NA, NA	148270.000, 1237720.000	148270.000, 1237720.000	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537691

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 112 of ?)

Lab: Madison
Biomarker: Total NNAL (pmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4146.440, 4146.440	4146.440, 4146.440	100.380, 100.380	31.118, 27.389	54.205, 42.228
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	20.8879, 14.7700	42.6290, 24.6118
	MEDIAN	NA	4146.440	4146.440	100.380	31.118	45.888
	MIN, MAX	NA, NA	4146.440, 4146.440	4146.440, 4146.440	100.380, 100.380	16.348, 45.888	16.348, 100.380
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	16.348, 45.888	16.348, 100.380
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	28	45	28	33	61
	MEAN, GEO MEAN	3843.040, 2433.210	4350.960, 3137.240	4159.080, 2850.060	86.609, 52.996	57.620, 53.476	70.927, 53.255
	SD, SE	2911.7300, 706.1980	2950.2500, 557.5460	2913.0900, 434.2570	158.8750, 30.0245	21.9896, 3.8279	108.7590, 13.9252
	MEDIAN	2529.220	3830.820	3752.440	42.733	54.492	51.624
	MIN, MAX	40.439, 9963.109	165.627, 11030.390	40.439, 11030.390	15.200, 869.893	22.944, 96.078	15.200, 869.893
	5%, 95%	40.439, 9963.110	177.458, 10735.300	177.458, 9963.110	18.642, 198.963	27.533, 93.210	22.944, 96.078
	BLQ Values Included	1	0	1	23	32	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	39.292, 39.292	39.292, 39.292
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	39.292	39.292
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	39.292, 39.292	39.292, 39.292
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3433.960, 1864.930	3433.960, 1864.930	23.231, 23.231	NA, NA	23.231, 23.231
	SD, SE	NA, NA	4352.1500, 2512.7100	4352.1500, 2512.7100	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1230.950	1230.950	23.231	NA	23.231
	MIN, MAX	NA, NA	623.790, 8447.144	623.790, 8447.144	23.231, 23.231	NA, NA	23.231, 23.231
	5%, 95%	NA, NA	623.790, 8447.140	623.790, 8447.140	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 113 of ?)

Lab: Madison
Biomarker: Total NNAL (pmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4436.280, 4436.280	4436.280, 4436.280	83.459, 83.459	44.712, 42.437	57.628, 53.168
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	19.9150, 14.0820	26.4338, 15.2616
	MEDIAN	NA	4436.280	4436.280	83.459	44.712	58.794
	MIN, MAX	NA, NA	4436.280, 4436.280	4436.280, 4436.280	83.459, 83.459	30.630, 58.794	30.630, 83.459
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	30.630, 58.794	30.630, 83.459
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	3732.650, 2316.290	5134.230, 3933.480	4566.920, 3174.590	65.900, 55.048	73.929, 64.255	70.244, 59.852
	SD, SE	2989.2700, 725.0040	3681.3700, 736.2730	3450.3800, 532.4050	52.4446, 9.9111	50.2471, 8.7469	50.9953, 6.5293
	MEDIAN	2584.690	4536.840	3938.220	51.337	58.794	57.360
	MIN, MAX	30.057, 9923.031	271.169, 19341.821	30.057, 19341.821	21.510, 293.922	28.393, 253.655	21.510, 293.922
	5%, 95%	30.057, 9923.030	466.146, 9380.650	466.146, 9388.690	21.510, 134.834	34.416, 242.819	30.745, 135.943
	BLQ Values Included	1	0	1	24	30	54
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	49.760, 49.760	49.760, 49.760
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	49.760	49.760
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	49.760, 49.760	49.760, 49.760
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1607.980, 1201.070	1607.980, 1201.070	41.012, 41.012	NA, NA	41.012, 41.012
	SD, SE	NA, NA	1541.1100, 889.7610	1541.1100, 889.7610	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	793.671	793.671	41.012	NA	41.012
	MIN, MAX	NA, NA	644.841, 3385.424	644.841, 3385.424	41.012, 41.012	NA, NA	41.012, 41.012
	5%, 95%	NA, NA	644.841, 3385.420	644.841, 3385.420	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 114 of ?)

Lab: Madison
Biomarker: Total NNAL (pmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4291.360, 4291.360	4291.360, 4291.360	91.920, 91.920	37.915, 37.913	55.917, 50.933
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4865, 0.3440	31.1817, 18.0028
	MEDIAN	NA	4291.360	4291.360	91.920	37.915	38.259
	MIN, MAX	NA, NA	4291.360, 4291.360	4291.360, 4291.360	91.920, 91.920	37.571, 38.259	37.571, 91.920
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	37.571, 38.259	37.571, 91.920
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3842.930, 2479.030	4569.820, 3462.790	4285.380, 3038.300	76.255, 56.379	65.775, 60.183	70.585, 58.406
	SD, SE	2880.5200, 678.9450	2856.0600, 539.7440	2856.1300, 421.1130	88.4070, 16.7073	30.3905, 5.2903	63.5406, 8.1355
	MEDIAN	2963.140	4087.570	4014.100	46.749	60.515	53.747
	MIN, MAX	35.248, 9943.070	224.314, 11798.000	35.248, 11798.000	18.355, 464.702	30.592, 161.920	18.355, 464.702
	5%, 95%	35.248, 9943.070	315.887, 10205.500	315.887, 9943.070	21.940, 246.443	30.831, 146.187	30.592, 146.187
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	44.526, 44.526	44.526, 44.526
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	44.526	44.526
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	44.526, 44.526	44.526, 44.526
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2520.970, 1578.440	2520.970, 1578.440	32.122, 32.122	NA, NA	32.122, 32.122
	SD, SE	NA, NA	2942.6600, 1698.9400	2942.6600, 1698.9400	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	937.894	937.894	32.122	NA	32.122
	MIN, MAX	NA, NA	708.731, 5916.280	708.731, 5916.280	32.122, 32.122	NA, NA	32.122, 32.122
	5%, 95%	NA, NA	708.731, 5916.280	708.731, 5916.280	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 115 of ?)

Lab: Madison
Biomarker: Total NNAL (pg/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	592.913, 592.913	592.913, 592.913	8.235, 8.235	3.984, 3.603	5.401, 4.746
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.4020, 1.6985	2.9850, 1.7234
	MEDIAN	NA	592.913	592.913	8.235	3.984	5.682
	MIN, MAX	NA, NA	592.913, 592.913	592.913, 592.913	8.235, 8.235	2.285, 5.682	2.285, 8.235
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	2.285, 5.682	2.285, 8.235
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	28	45	28	33	61
	MEAN, GEO MEAN	632.351, 388.963	838.077, 590.562	760.358, 504.374	11.522, 6.213	10.417, 9.685	10.924, 7.900
	SD, SE	604.3900, 146.5860	586.3170, 110.8030	594.9410, 88.6886	24.7595, 4.6791	3.8542, 0.6709	16.8552, 2.1581
	MEDIAN	339.746	637.941	633.056	5.013	9.600	9.202
	MIN, MAX	7.958, 2575.145	18.519, 2476.718	7.958, 2575.145	1.932, 134.956	3.883, 18.634	1.932, 134.956
	5%, 95%	7.958, 2575.150	30.892, 2010.240	30.892, 2010.240	2.103, 25.707	4.009, 17.699	2.911, 17.699
	BLQ Values Included	1	0	1	23	32	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	9.188, 9.188	9.188, 9.188
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	9.188	9.188
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	9.188, 9.188	9.188, 9.188
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	451.867, 275.727	451.867, 275.727	4.418, 4.418	NA, NA	4.418, 4.418
	SD, SE	NA, NA	537.3920, 310.2630	537.3920, 310.2630	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	166.031	166.031	4.418	NA	4.418
	MIN, MAX	NA, NA	117.801, 1071.768	117.801, 1071.768	4.418, 4.418	NA, NA	4.418, 4.418
	5%, 95%	NA, NA	117.801, 1071.770	117.801, 1071.770	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 116 of ?)

Lab: Madison
Biomarker: Total NNAL (pg/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	558.842, 558.842	558.842, 558.842	7.605, 7.605	6.303, 5.783	6.737, 6.335
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	3.5468, 2.5080	2.6182, 1.5116
	MEDIAN	NA	558.842	558.842	7.605	6.303	7.605
	MIN, MAX	NA, NA	558.842, 558.842	558.842, 558.842	7.605, 7.605	3.795, 8.811	3.795, 8.811
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.795, 8.811	3.795, 8.811
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	533.334, 349.698	880.309, 677.525	739.866, 518.400	7.724, 6.200	14.446, 11.942	11.360, 8.839
	SD, SE	387.2530, 93.9228	570.6610, 114.1320	528.0750, 81.4837	6.3914, 1.2079	10.7429, 1.8701	9.5574, 1.2237
	MEDIAN	381.623	788.146	586.533	5.843	10.657	8.380
	MIN, MAX	5.525, 1261.017	56.481, 2275.640	5.525, 2275.640	2.158, 34.375	3.259, 53.767	2.158, 53.767
	5%, 95%	5.525, 1261.020	65.031, 2024.780	65.031, 2004.780	2.413, 15.074	5.464, 41.549	2.923, 30.000
	BLQ Values Included	1	0	1	24	30	54
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	13.793, 13.793	13.793, 13.793
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	13.793	13.793
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	13.793, 13.793	13.793, 13.793
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	525.222, 322.859	525.222, 322.859	9.390, 9.390	NA, NA	9.390, 9.390
	SD, SE	NA, NA	621.0020, 358.5360	621.0020, 358.5360	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	195.387	195.387	9.390	NA	9.390
	MIN, MAX	NA, NA	138.733, 1241.547	138.733, 1241.547	9.390, 9.390	NA, NA	9.390, 9.390
	5%, 95%	NA, NA	138.733, 1241.550	138.733, 1241.550	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 117 of ?)

Lab: Madison
Biomarker: Total NNAL (pg/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	575.878, 575.878	575.878, 575.878	7.920, 7.920	5.144, 5.128	6.069, 5.927
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.5720, 0.4045	1.6533, 0.9545
	MEDIAN	NA	575.878	575.878	7.920	5.144	5.548
	MIN, MAX	NA, NA	575.878, 575.878	575.878, 575.878	7.920, 7.920	4.739, 5.548	4.739, 7.920
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	4.739, 5.548	4.739, 7.920
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	581.550, 377.045	851.036, 630.834	745.585, 515.763	9.623, 6.586	12.432, 11.133	11.143, 8.749
	SD, SE	470.7100, 110.9470	559.1560, 105.6710	537.5680, 79.2600	13.1439, 2.4840	6.2289, 1.0843	10.0213, 1.2831
	MEDIAN	389.237	675.845	639.570	5.142	10.812	9.121
	MIN, MAX	6.742, 1877.500	41.775, 2250.750	6.742, 2250.750	2.131, 70.371	3.634, 30.459	2.131, 70.371
	5%, 95%	6.742, 1877.500	43.687, 2007.510	43.687, 1877.500	2.364, 30.041	5.423, 27.562	3.508, 27.562
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	11.491, 11.491	11.491, 11.491
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	11.491	11.491
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	11.491, 11.491	11.491, 11.491
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	488.545, 302.207	488.545, 302.207	6.904, 6.904	NA, NA	6.904, 6.904
	SD, SE	NA, NA	578.6080, 334.0600	578.6080, 334.0600	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	156.594	156.594	6.904	NA	6.904
	MIN, MAX	NA, NA	152.382, 1156.660	152.382, 1156.660	6.904, 6.904	NA, NA	6.904, 6.904
	5%, 95%	NA, NA	152.382, 1156.660	152.382, 1156.660	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Total NNAL (pmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.834, 2.834	2.834, 2.834	0.039, 0.039	0.019, 0.017	0.026, 0.023
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0113, 0.0080	0.0140, 0.0081
	MEDIAN	NA	2.834	2.834	0.039	0.019	0.027
	MIN, MAX	NA, NA	2.834, 2.834	2.834, 2.834	0.039, 0.039	0.011, 0.027	0.011, 0.039
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.011, 0.027	0.011, 0.039
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	28	45	28	33	61
	MEAN, GEO MEAN	3.023, 1.859	4.006, 2.824	3.635, 2.411	0.055, 0.030	0.050, 0.046	0.052, 0.038
	SD, SE	2.8890, 0.7007	2.8026, 0.5296	2.8438, 0.4239	0.1183, 0.0224	0.0185, 0.0032	0.0806, 0.0103
	MEDIAN	1.624	3.050	3.026	0.024	0.046	0.044
	MIN, MAX	0.038, 12.309	0.089, 11.839	0.038, 12.309	0.009, 0.645	0.019, 0.089	0.009, 0.645
	5%, 95%	0.038, 12.309	0.148, 9.609	0.148, 9.609	0.010, 0.123	0.019, 0.085	0.014, 0.085
	BLQ Values Included	1	0	1	23	32	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.044, 0.044	0.044, 0.044
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.044	0.044
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.044, 0.044	0.044, 0.044
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2.160, 1.318	2.160, 1.318	0.021, 0.021	NA, NA	0.021, 0.021
	SD, SE	NA, NA	2.5686, 1.4830	2.5686, 1.4830	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.794	0.794	0.021	NA	0.021
	MIN, MAX	NA, NA	0.563, 5.123	0.563, 5.123	0.021, 0.021	NA, NA	0.021, 0.021
	5%, 95%	NA, NA	0.563, 5.123	0.563, 5.123	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 119 of ?)

Lab: Madison
Biomarker: Total NNAL (pmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.671, 2.671	2.671, 2.671	0.036, 0.036	0.030, 0.027	0.032, 0.030
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0170, 0.0120	0.0125, 0.0072
	MEDIAN	NA	2.671	2.671	0.036	0.030	0.036
	MIN, MAX	NA, NA	2.671, 2.671	2.671, 2.671	0.036, 0.036	0.018, 0.042	0.018, 0.042
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.042	0.018, 0.042
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	2.549, 1.670	4.208, 3.239	3.537, 2.477	0.037, 0.030	0.069, 0.057	0.054, 0.042
	SD, SE	1.8512, 0.4490	2.7278, 0.5456	2.5242, 0.3895	0.0305, 0.0058	0.0513, 0.0089	0.0457, 0.0058
	MEDIAN	1.824	3.767	2.804	0.028	0.051	0.040
	MIN, MAX	0.026, 6.028	0.270, 10.878	0.026, 10.878	0.010, 0.164	0.016, 0.257	0.010, 0.257
	5%, 95%	0.026, 6.028	0.311, 9.678	0.311, 9.583	0.012, 0.072	0.026, 0.199	0.014, 0.143
	BLQ Values Included	1	0	1	24	30	54
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.066, 0.066	0.066, 0.066
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.066	0.066
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.066, 0.066	0.066, 0.066
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2.511, 1.543	2.511, 1.543	0.045, 0.045	NA, NA	0.045, 0.045
	SD, SE	NA, NA	2.9687, 1.7140	2.9687, 1.7140	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.934	0.934	0.045	NA	0.045
	MIN, MAX	NA, NA	0.663, 5.935	0.663, 5.935	0.045, 0.045	NA, NA	0.045, 0.045
	5%, 95%	NA, NA	0.663, 5.935	0.663, 5.935	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537699

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Total NNAL (pmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2.753, 2.753	2.753, 2.753	0.038, 0.038	0.025, 0.025	0.029, 0.029
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0028, 0.0020	0.0078, 0.0045
	MEDIAN	NA	2.753	2.753	0.038	0.025	0.027
	MIN, MAX	NA, NA	2.753, 2.753	2.753, 2.753	0.038, 0.038	0.023, 0.027	0.023, 0.038
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.023, 0.027	0.023, 0.038
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2.780, 1.802	4.068, 3.016	3.564, 2.465	0.046, 0.032	0.060, 0.054	0.054, 0.042
	SD, SE	2.2501, 0.5304	2.6728, 0.5051	2.5696, 0.3789	0.0629, 0.0119	0.0297, 0.0052	0.0479, 0.0061
	MEDIAN	1.861	3.231	3.058	0.025	0.052	0.044
	MIN, MAX	0.032, 8.975	0.200, 10.759	0.032, 10.759	0.010, 0.337	0.018, 0.146	0.010, 0.337
	5%, 95%	0.032, 8.975	0.209, 9.596	0.209, 8.975	0.011, 0.144	0.026, 0.132	0.017, 0.132
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.055, 0.055	0.055, 0.055
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.055	0.055
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.055, 0.055	0.055, 0.055
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2.336, 1.445	2.336, 1.445	0.033, 0.033	NA, NA	0.033, 0.033
	SD, SE	NA, NA	2.7655, 1.5967	2.7655, 1.5967	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.749	0.749	0.033	NA	0.033
	MIN, MAX	NA, NA	0.729, 5.529	0.729, 5.529	0.033, 0.033	NA, NA	0.033, 0.033
	5%, 95%	NA, NA	0.729, 5.529	0.729, 5.529	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537700

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 121 of ?)

Lab: Madison
Biomarker: Free NNAL (pg/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	319872.000, 319872.000	319872.000, 319872.000	18000.000, 18000.000	6510.000, 5729.920	10340.000, 8391.830
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4369.9200, 3090.0000	7318.1100, 4225.1200
	MEDIAN	NA	319872.000	319872.000	18000.000	6510.000	9600.000
	MIN, MAX	NA, NA	319872.000, 319872.000	319872.000, 319872.000	18000.000, 18000.000	3420.000, 9600.000	3420.000, 18000.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3420.000, 9600.000	3420.000, 18000.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	191275.000, 138941.000	271940.000, 207056.000	240375.000, 177130.000	10339.100, 9167.310	12926.700, 11578.700	11738.900, 10401.800
	SD, SE	118708.0000, 27979.8000	179741.0000, 33967.9000	162148.0000, 23907.4000	5308.1400, 1003.1400	6486.9200, 1129.2300	6067.3300, 776.8410
	MEDIAN	192779.000	234059.000	224364.000	8190.000	11400.000	9420.000
	MIN, MAX	8460.000, 409840.000	16500.000, 671265.000	8460.000, 671265.000	3180.000, 22800.000	4800.000, 30796.800	3180.000, 30796.800
	5%, 95%	8460.000, 409840.000	23940.000, 649460.000	23940.000, 637980.000	3900.000, 20100.000	5760.000, 27840.000	5280.000, 22800.000
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8220.000, 8220.000	8220.000, 8220.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8220.000	8220.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8220.000, 8220.000	8220.000, 8220.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	362417.000, 225541.000	362417.000, 225541.000	4860.000, 4860.000	NA, NA	4860.000, 4860.000
	SD, SE	NA, NA	424692.0000, 245196.0000	424692.0000, 245196.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	135716.000	135716.000	4860.000	NA	4860.000
	MIN, MAX	NA, NA	99180.000, 852355.000	99180.000, 852355.000	4860.000, 4860.000	NA, NA	4860.000, 4860.000
	5%, 95%	NA, NA	99180.000, 852355.000	99180.000, 852355.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537701

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Free NNAL (pg/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	374334.000, 374334.000	374334.000, 374334.000	17460.000, 17460.000	9354.000, 8877.970	12056.000, 11123.100
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4166.2700, 2946.0000	5530.0400, 3192.7700
	MEDIAN	NA	374334.000	374334.000	17460.000	9354.000	12300.000
	MIN, MAX	NA, NA	374334.000, 374334.000	374334.000, 374334.000	17460.000, 17460.000	6408.000, 12300.000	6408.000, 17460.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6408.000, 12300.000	6408.000, 17460.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	229255.000, 150668.000	323390.000, 280284.000	285288.000, 218014.000	15661.800, 12423.800	13210.500, 12325.700	14335.700, 12370.700
	SD, SE	184405.0000, 44724.9000	162241.0000, 32448.2000	175686.0000, 27108.9000	13078.4000, 2471.5900	4976.4500, 866.2880	9575.7600, 1226.0500
	MEDIAN	162848.000	286356.000	241481.000	11400.000	12300.000	12180.000
	MIN, MAX	6288.000, 573980.000	52452.000, 781704.000	6288.000, 781704.000	4500.000, 57240.000	5640.000, 28440.000	4500.000, 57240.000
	5%, 95%	6288.000, 573980.000	83904.000, 535470.000	52452.000, 558700.000	4500.000, 52910.000	5940.000, 20100.000	5940.000, 28440.000
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10410.000, 10410.000	10410.000, 10410.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10410.000	10410.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10410.000, 10410.000	10410.000, 10410.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	149746.000, 108274.000	149746.000, 108274.000	8580.000, 8580.000	NA, NA	8580.000, 8580.000
	SD, SE	NA, NA	145303.0000, 83890.7000	145303.0000, 83890.7000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	87500.000	87500.000	8580.000	NA	8580.000
	MIN, MAX	NA, NA	45936.000, 315802.800	45936.000, 315802.800	8580.000, 8580.000	NA, NA	8580.000, 8580.000
	5%, 95%	NA, NA	45936.000, 315803.000	45936.000, 315803.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537702

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Free NNAL (pg/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	347103.000, 347103.000	347103.000, 347103.000	17730.000, 17730.000	7932.000, 7931.670	11198.000, 10370.800
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	101.8230, 72.0000	5657.3400, 3266.2600
	MEDIAN	NA	347103.000	347103.000	17730.000	7932.000	8004.000
	MIN, MAX	NA, NA	347103.000, 347103.000	347103.000, 347103.000	17730.000, 17730.000	7860.000, 8004.000	7860.000, 17730.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	7860.000, 8004.000	7860.000, 17730.000
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	210261.000, 149954.000	288311.000, 239091.000	257770.000, 199197.000	13000.400, 11447.600	13068.600, 12106.500	13037.300, 11799.400
	SD, SE	140302.0000, 33069.5000	159886.0000, 30215.7000	155749.0000, 22964.0000	7095.5200, 1340.9300	5308.2200, 924.0420	6138.8000, 785.9930
	MEDIAN	185851.000	262597.000	239327.000	10033.500	12660.000	11400.000
	MIN, MAX	7374.000, 426577.000	34476.000, 589956.000	7374.000, 589956.000	3840.000, 32310.000	5910.000, 28140.000	3840.000, 32310.000
	5%, 95%	7374.000, 426577.000	53922.000, 588893.000	47776.000, 568785.000	5280.000, 29095.000	6450.000, 24998.400	6450.000, 24998.400
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	9315.000, 9315.000	9315.000, 9315.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	9315.000	9315.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	9315.000, 9315.000	9315.000, 9315.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	256082.000, 170445.000	256082.000, 170445.000	6720.000, 6720.000	NA, NA	6720.000, 6720.000
	SD, SE	NA, NA	284057.0000, 164000.0000	284057.0000, 164000.0000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	93340.000	93340.000	6720.000	NA	6720.000
	MIN, MAX	NA, NA	90826.000, 584079.000	90826.000, 584079.000	6720.000, 6720.000	NA, NA	6720.000, 6720.000
	5%, 95%	NA, NA	90826.000, 584079.000	90826.000, 584079.000	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537703

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Free NNAL (pmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1528.990, 1528.990	1528.990, 1528.990	86.040, 86.040	31.118, 27.389	49.425, 40.113
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	20.8879, 14.7700	34.9804, 20.1959
	MEDIAN	NA	1528.990	1528.990	86.040	31.118	45.888
	MIN, MAX	NA, NA	1528.988, 1528.988	1528.988, 1528.988	86.040, 86.040	16.348, 45.888	16.348, 86.040
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	16.348, 45.888	16.348, 86.040
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	914.293, 664.139	1299.870, 989.728	1148.990, 846.681	49.421, 43.820	61.789, 55.346	56.112, 49.720
	SD, SE	567.4250, 133.7430	859.1640, 162.3670	775.0680, 114.2770	25.3730, 4.7950	31.0075, 5.3977	29.0019, 3.7133
	MEDIAN	921.484	1118.800	1072.460	39.148	54.492	45.028
	MIN, MAX	40.439, 1959.035	78.870, 3208.647	40.439, 3208.647	15.200, 108.984	22.944, 147.209	15.200, 147.209
	5%, 95%	40.439, 1959.040	114.433, 3104.420	114.433, 3049.540	18.642, 96.078	27.533, 133.075	25.238, 108.984
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	39.292, 39.292	39.292, 39.292
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	39.292	39.292
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	39.292, 39.292	39.292, 39.292
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1732.350, 1078.080	1732.350, 1078.080	23.231, 23.231	NA, NA	23.231, 23.231
	SD, SE	NA, NA	2030.0300, 1172.0400	2030.0300, 1172.0400	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	648.722	648.722	23.231	NA	23.231
	MIN, MAX	NA, NA	474.080, 4074.257	474.080, 4074.257	23.231, 23.231	NA, NA	23.231, 23.231
	5%, 95%	NA, NA	474.080, 4074.260	474.080, 4074.260	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537704

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 125 of ?)

Lab: Madison
Biomarker: Free NNAL (pmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1789.320, 1789.320	1789.320, 1789.320	83.459, 83.459	44.712, 42.437	57.628, 53.168
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	19.9150, 14.0820	26.4338, 15.2616
	MEDIAN	NA	1789.320	1789.320	83.459	44.712	58.794
	MIN, MAX	NA, NA	1789.317, 1789.317	1789.317, 1789.317	83.459, 83.459	30.630, 58.794	30.630, 83.459
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	30.630, 58.794	30.630, 83.459
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1095.840, 720.195	1545.810, 1339.760	1363.680, 1042.110	74.864, 59.386	63.146, 58.917	68.525, 59.132
	SD, SE	881.4580, 213.7850	775.5130, 155.1030	839.7790, 129.5810	62.5148, 11.8142	23.7874, 4.1409	45.7721, 5.8605
	MEDIAN	778.413	1368.780	1154.280	54.492	58.794	58.220
	MIN, MAX	30.057, 2743.624	250.721, 3736.545	30.057, 3736.545	21.510, 273.607	26.959, 135.943	21.510, 273.607
	5%, 95%	30.057, 2743.620	401.061, 2559.550	250.721, 2670.590	21.510, 252.910	28.393, 96.078	28.393, 135.943
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	49.760, 49.760	49.760, 49.760
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	49.760	49.760
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	49.760, 49.760	49.760, 49.760
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	715.787, 517.551	715.787, 517.551	41.012, 41.012	NA, NA	41.012, 41.012
	SD, SE	NA, NA	694.5480, 400.9980	694.5480, 400.9980	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	418.250	418.250	41.012	NA	41.012
	MIN, MAX	NA, NA	219.574, 1509.537	219.574, 1509.537	41.012, 41.012	NA, NA	41.012, 41.012
	5%, 95%	NA, NA	219.574, 1509.540	219.574, 1509.540	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537705

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Free NNAL (pmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1659.150, 1659.150	1659.150, 1659.150	84.750, 84.750	37.915, 37.913	53.527, 49.573
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.4865, 0.3440	27.0424, 15.6129
	MEDIAN	NA	1659.150	1659.150	84.750	37.915	38.259
	MIN, MAX	NA, NA	1659.150, 1659.150	1659.150, 1659.150	84.750, 84.750	37.571, 38.259	37.571, 84.750
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	37.571, 38.259	37.571, 84.750
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1005.050, 716.780	1378.130, 1142.850	1232.140, 952.161	62.142, 54.720	62.468, 57.869	62.318, 56.402
	SD, SE	670.6430, 158.0720	764.2570, 144.4310	744.4820, 109.7680	33.9166, 6.4096	25.3733, 4.4169	29.3435, 3.7570
	MEDIAN	888.366	1255.220	1143.980	47.961	60.515	54.492
	MIN, MAX	35.248, 2039.040	164.796, 2819.990	35.248, 2819.990	18.355, 154.442	28.250, 134.509	18.355, 154.442
	5%, 95%	35.248, 2039.040	257.747, 2814.910	228.369, 2718.790	25.239, 139.074	30.831, 119.493	30.831, 119.493
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	44.526, 44.526	44.526, 44.526
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	44.526	44.526
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	44.526, 44.526	44.526, 44.526
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1224.070, 814.725	1224.070, 814.725	32.122, 32.122	NA, NA	32.122, 32.122
	SD, SE	NA, NA	1357.7900, 783.9220	1357.7900, 783.9220	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	446.165	446.165	32.122	NA	32.122
	MIN, MAX	NA, NA	434.148, 2791.900	434.148, 2791.900	32.122, 32.122	NA, NA	32.122, 32.122
	5%, 95%	NA, NA	434.148, 2791.900	434.148, 2791.900	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537706

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Free NNAL (pg/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	218.635, 218.635	218.635, 218.635	7.059, 7.059	3.984, 3.603	5.009, 4.509
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.4020, 1.6985	2.4572, 1.4187
	MEDIAN	NA	218.635	218.635	7.059	3.984	5.682
	MIN, MAX	NA, NA	218.635, 218.635	218.635, 218.635	7.059, 7.059	2.285, 5.682	2.285, 7.059
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	2.285, 5.682	2.285, 7.059
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	160.048, 105.095	255.881, 186.309	218.381, 148.914	5.957, 5.137	11.118, 10.024	8.749, 7.375
	SD, SE	171.2220, 40.3573	182.2060, 34.4337	182.2930, 26.8777	3.4402, 0.6501	5.3328, 0.9283	5.2171, 0.6680
	MEDIAN	105.373	208.248	178.751	4.462	9.600	8.915
	MIN, MAX	7.958, 767.052	12.795, 813.359	7.958, 813.359	1.932, 14.815	3.436, 29.814	1.932, 29.814
	5%, 95%	7.958, 767.052	13.730, 612.755	13.730, 612.755	2.683, 11.788	3.883, 20.782	2.973, 17.143
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	9.188, 9.188	9.188, 9.188
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	9.188	9.188
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	9.188, 9.188	9.188, 9.188
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	231.323, 159.393	231.323, 159.393	4.418, 4.418	NA, NA	4.418, 4.418
	SD, SE	NA, NA	247.3530, 142.8090	247.3530, 142.8090	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	89.529	89.529	4.418	NA	4.418
	MIN, MAX	NA, NA	87.500, 516.939	87.500, 516.939	4.418, 4.418	NA, NA	4.418, 4.418
	5%, 95%	NA, NA	87.500, 516.939	87.500, 516.939	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pg/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	225.402, 225.402	225.402, 225.402	7.605, 7.605	6.303, 5.783	6.737, 6.335
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	3.5468, 2.5080	2.6182, 1.5116
	MEDIAN	NA	225.402	225.402	7.605	6.303	7.605
	MIN, MAX	NA, NA	225.402, 225.402	225.402, 225.402	7.605, 7.605	3.795, 8.811	3.795, 8.811
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3.795, 8.811	3.795, 8.811
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	153.041, 108.730	276.250, 230.768	226.380, 170.172	8.677, 6.689	12.411, 10.950	10.697, 8.733
	SD, SE	106.2860, 25.7781	165.6020, 33.1205	155.5900, 24.0080	7.1996, 1.3606	6.5072, 1.1328	7.0306, 0.9002
	MEDIAN	109.091	225.497	194.555	6.049	10.657	9.539
	MIN, MAX	5.525, 368.503	52.222, 724.324	5.525, 724.324	2.158, 30.264	3.259, 30.000	2.158, 30.264
	5%, 95%	5.525, 368.503	55.951, 547.012	49.740, 538.801	2.413, 29.578	3.995, 29.412	2.923, 29.412
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	13.793, 13.793	13.793, 13.793
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	13.793	13.793
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	13.793, 13.793	13.793, 13.793
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	234.601, 139.123	234.601, 139.123	9.390, 9.390	NA, NA	9.390, 9.390
	SD, SE	NA, NA	277.6600, 160.3070	277.6600, 160.3070	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	102.965	102.965	9.390	NA	9.390
	MIN, MAX	NA, NA	47.240, 553.597	47.240, 553.597	9.390, 9.390	NA, NA	9.390, 9.390
	5%, 95%	NA, NA	47.240, 553.597	47.240, 553.597	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pg/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	222.019, 222.019	222.019, 222.019	7.332, 7.332	5.144, 5.128	5.873, 5.777
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.5720, 0.4045	1.3267, 0.7660
	MEDIAN	NA	222.019	222.019	7.332	5.144	5.548
	MIN, MAX	NA, NA	222.019, 222.019	222.019, 222.019	7.332, 7.332	4.739, 5.548	4.739, 7.332
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	4.739, 5.548	4.739, 7.332
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	155.884, 110.331	265.223, 208.272	222.438, 162.426	7.317, 6.279	11.764, 10.709	9.723, 8.382
	SD, SE	125.4040, 29.5580	176.2670, 33.3112	165.8120, 24.4477	4.1718, 0.7884	5.0121, 0.8725	5.1209, 0.6557
	MEDIAN	121.636	207.009	185.127	5.327	10.812	9.121
	MIN, MAX	6.742, 522.399	32.976, 768.842	6.742, 768.842	2.364, 17.426	3.348, 23.043	2.364, 23.043
	5%, 95%	6.742, 522.399	34.373, 612.755	34.373, 522.399	2.693, 16.420	4.532, 21.741	3.185, 19.673
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	11.491, 11.491	11.491, 11.491
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	11.491	11.491
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	11.491, 11.491	11.491, 11.491
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	232.962, 151.406	232.962, 151.406	6.904, 6.904	NA, NA	6.904, 6.904
	SD, SE	NA, NA	262.2030, 151.3830	262.2030, 151.3830	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	96.247	96.247	6.904	NA	6.904
	MIN, MAX	NA, NA	67.370, 535.268	67.370, 535.268	6.904, 6.904	NA, NA	6.904, 6.904
	5%, 95%	NA, NA	67.370, 535.268	67.370, 535.268	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537709

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.045, 1.045	1.045, 1.045	0.034, 0.034	0.019, 0.017	0.024, 0.022
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0113, 0.0080	0.0118, 0.0068
	MEDIAN	NA	1.045	1.045	0.034	0.019	0.027
	MIN, MAX	NA, NA	1.045, 1.045	1.045, 1.045	0.034, 0.034	0.011, 0.027	0.011, 0.034
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.011, 0.027	0.011, 0.034
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	0.765, 0.502	1.223, 0.891	1.044, 0.712	0.029, 0.025	0.053, 0.048	0.042, 0.035
	SD, SE	0.8185, 0.1929	0.8710, 0.1646	0.8714, 0.1285	0.0165, 0.0031	0.0256, 0.0045	0.0250, 0.0032
	MEDIAN	0.504	0.996	0.855	0.022	0.046	0.043
	MIN, MAX	0.038, 3.667	0.061, 3.888	0.038, 3.888	0.009, 0.071	0.016, 0.143	0.009, 0.143
	5%, 95%	0.038, 3.667	0.066, 2.929	0.066, 2.929	0.013, 0.056	0.019, 0.099	0.014, 0.082
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.044, 0.044	0.044, 0.044
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.044	0.044
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.044, 0.044	0.044, 0.044
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.106, 0.762	1.106, 0.762	0.021, 0.021	NA, NA	0.021, 0.021
	SD, SE	NA, NA	1.1824, 0.6827	1.1824, 0.6827	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.428	0.428	0.021	NA	0.021
	MIN, MAX	NA, NA	0.418, 2.471	0.418, 2.471	0.021, 0.021	NA, NA	0.021, 0.021
	5%, 95%	NA, NA	0.418, 2.471	0.418, 2.471	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 131 of ?)

Lab: Madison
Biomarker: Free NNAL (pmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.077, 1.077	1.077, 1.077	0.036, 0.036	0.030, 0.027	0.032, 0.030
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0170, 0.0120	0.0125, 0.0072
	MEDIAN	NA	1.077	1.077	0.036	0.030	0.036
	MIN, MAX	NA, NA	1.077, 1.077	1.077, 1.077	0.036, 0.036	0.018, 0.042	0.018, 0.042
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.018, 0.042	0.018, 0.042
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	0.731, 0.519	1.320, 1.103	1.082, 0.813	0.041, 0.032	0.059, 0.052	0.051, 0.042
	SD, SE	0.5080, 0.1232	0.7916, 0.1583	0.7437, 0.1148	0.0344, 0.0065	0.0310, 0.0054	0.0336, 0.0043
	MEDIAN	0.521	1.078	0.930	0.029	0.051	0.046
	MIN, MAX	0.026, 1.761	0.250, 3.462	0.026, 3.462	0.010, 0.145	0.016, 0.143	0.010, 0.145
	5%, 95%	0.026, 1.761	0.267, 2.615	0.238, 2.575	0.012, 0.141	0.019, 0.141	0.014, 0.141
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.066, 0.066	0.066, 0.066
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.066	0.066
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.066, 0.066	0.066, 0.066
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.121, 0.665	1.121, 0.665	0.045, 0.045	NA, NA	0.045, 0.045
	SD, SE	NA, NA	1.3271, 0.7662	1.3271, 0.7662	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.492	0.492	0.045	NA	0.045
	MIN, MAX	NA, NA	0.226, 2.646	0.226, 2.646	0.045, 0.045	NA, NA	0.045, 0.045
	5%, 95%	NA, NA	0.226, 2.646	0.226, 2.646	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.061, 1.061	1.061, 1.061	0.035, 0.035	0.025, 0.025	0.028, 0.028
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0028, 0.0020	0.0061, 0.0035
	MEDIAN	NA	1.061	1.061	0.035	0.025	0.027
	MIN, MAX	NA, NA	1.061, 1.061	1.061, 1.061	0.035, 0.035	0.023, 0.027	0.023, 0.035
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.023, 0.027	0.023, 0.035
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	0.745, 0.527	1.268, 0.996	1.064, 0.777	0.035, 0.030	0.056, 0.051	0.047, 0.040
	SD, SE	0.5996, 0.1413	0.8426, 0.1592	0.7926, 0.1169	0.0200, 0.0038	0.0239, 0.0042	0.0244, 0.0031
	MEDIAN	0.582	0.990	0.885	0.026	0.052	0.044
	MIN, MAX	0.032, 2.498	0.158, 3.675	0.032, 3.675	0.011, 0.084	0.016, 0.110	0.011, 0.110
	5%, 95%	0.032, 2.498	0.164, 2.929	0.164, 2.498	0.013, 0.079	0.022, 0.104	0.015, 0.094
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.055, 0.055	0.055, 0.055
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.055	0.055
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.055, 0.055	0.055, 0.055
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.114, 0.724	1.114, 0.724	0.033, 0.033	NA, NA	0.033, 0.033
	SD, SE	NA, NA	1.2536, 0.7238	1.2536, 0.7238	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.460	0.460	0.033	NA	0.033
	MIN, MAX	NA, NA	0.322, 2.559	0.322, 2.559	0.033, 0.033	NA, NA	0.033, 0.033
	5%, 95%	NA, NA	0.322, 2.559	0.322, 2.559	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject. then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537712

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 133 of ?)

Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2044.9, 2044.9	2044.9, 2044.9	4.8, 4.8	0.0, NA	1.6, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	2.77, 1.60
	MEDIAN	NA	2044.9	2044.9	4.8	0.0	0.0
	MIN, MAX	NA, NA	2044.9, 2044.9	2044.9, 2044.9	4.8, 4.8	0.0, 0.0	0.0, 4.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 0.0	0.0, 4.8
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	28	45	27	30	57
	MEAN, GEO MEAN	1950.1, NA	1969.2, 1184.9	1962.0, NA	40.5, NA	0.2, NA	19.3, NA
	SD, SE	2050.37, 497.29	1752.17, 331.13	1847.36, 275.39	167.92, 32.32	0.88, 0.16	116.21, 15.39
	MEDIAN	1543.0	1631.9	1564.5	0.0	0.0	0.0
	MIN, MAX	0.0, 7358.3	24.4, 7462.5	0.0, 7462.5	0.0, 859.0	0.0, 4.8	0.0, 859.0
	5%, 95%	0.0, 7358.3	35.9, 5458.8	35.9, 5782.8	0.0, 197.4	0.0, 0.0	0.0, 17.7
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.0, NA	0.0, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.0	0.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 0.0	0.0, 0.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	743.3, 330.9	743.3, 330.9	0.0, NA	NA, NA	0.0, NA
	SD, SE	NA, NA	918.10, 530.06	918.10, 530.06	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	393.4	393.4	0.0	NA	0.0
	MIN, MAX	NA, NA	51.6, 1784.9	51.6, 1784.9	0.0, 0.0	NA, NA	0.0, 0.0
	5%, 95%	NA, NA	51.6, 1784.9	51.6, 1784.9	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1982.7, 1982.7	1982.7, 1982.7	0.0, NA	0.0, NA	0.0, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1982.7	1982.7	0.0	0.0	0.0
	MIN, MAX	NA, NA	1982.7, 1982.7	1982.7, 1982.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 0.0	0.0, 0.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	26	33	59
	MEAN, GEO MEAN	1457.1, NA	2271.2, 1215.7	1941.7, NA	2.1, NA	5.6, NA	4.1, NA
	SD, SE	1136.78, 275.71	2342.60, 468.52	1969.84, 303.95	6.75, 1.32	20.06, 3.49	15.64, 2.04
	MEDIAN	1234.2	1443.6	1352.5	0.0	0.0	0.0
	MIN, MAX	0.0, 4514.7	11.0, 9536.6	0.0, 9536.6	0.0, 31.5	0.0, 99.9	0.0, 99.9
	5%, 95%	0.0, 4514.7	35.4, 7004.1	35.4, 5911.9	0.0, 12.4	0.0, 55.9	0.0, 31.5
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.0, NA	0.0, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.0	0.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 0.0	0.0, 0.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	860.0, 618.8	860.0, 618.8	0.0, NA	NA, NA	0.0, NA
	SD, SE	NA, NA	845.56, 488.18	845.56, 488.18	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	483.3	483.3	0.0	NA	0.0
	MIN, MAX	NA, NA	268.2, 1828.4	268.2, 1828.4	0.0, 0.0	NA, NA	0.0, 0.0
	5%, 95%	NA, NA	268.2, 1828.4	268.2, 1828.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 135 of 7)

Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2013.8, 2013.8	2013.8, 2013.8	2.4, 2.4	0.0, NA	0.8, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	1.39, 0.80
	MEDIAN	NA	2013.8	2013.8	2.4	0.0	0.0
	MIN, MAX	NA, NA	2013.8, 2013.8	2013.8, 2013.8	2.4, 2.4	0.0, 0.0	0.0, 2.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 0.0	0.0, 2.4
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1744.6, NA	2041.3, 1213.9	1925.2, NA	20.5, NA	2.9, NA	11.0, NA
	SD, SE	1455.58, 343.08	1796.22, 339.45	1660.62, 244.85	83.00, 15.69	10.03, 1.75	56.85, 7.28
	MEDIAN	1277.7	1626.1	1521.7	0.0	0.0	0.0
	MIN, MAX	0.0, 4879.9	23.5, 5778.3	0.0, 5778.3	0.0, 429.5	0.0, 50.0	0.0, 429.5
	5%, 95%	0.0, 4879.9	29.9, 5681.3	29.9, 5668.4	0.0, 114.5	0.0, 28.0	0.0, 28.0
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.0, NA	0.0, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.0	0.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.0, 0.0	0.0, 0.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	801.7, 502.2	801.7, 502.2	0.0, NA	NA, NA	0.0, NA
	SD, SE	NA, NA	881.45, 508.91	881.45, 508.91	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	438.4	438.4	0.0	NA	0.0
	MIN, MAX	NA, NA	159.9, 1806.7	159.9, 1806.7	0.0, 0.0	NA, NA	0.0, 0.0
	5%, 95%	NA, NA	159.9, 1806.7	159.9, 1806.7	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2617.470, 2617.470	2617.470, 2617.470	14.400, 14.400	0.000, NA	4.800, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	8.3138, 4.8000
	MEDIAN	NA	2617.470	2617.470	14.400	0.000	0.000
	MIN, MAX	NA, NA	2617.472, 2617.472	2617.472, 2617.472	14.400, 14.400	0.000, 0.000	0.000, 14.400
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 14.400
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	28	45	27	30	57
	MEAN, GEO MEAN	2904.960, NA	3051.100, 2048.040	2995.890, NA	40.543, NA	0.157, NA	19.287, NA
	SD, SE	2489.6700, 603.8330	2220.3600, 419.6090	2298.7700, 342.6810	163.7960, 31.5225	0.8588, 0.1568	113.4490, 15.0266
	MEDIAN	1833.190	2603.220	2416.280	0.000	0.000	0.000
	MIN, MAX	0.000, 8646.003	51.240, 8788.668	0.000, 8788.668	0.000, 841.820	0.000, 4.704	0.000, 841.820
	5%, 95%	0.000, 8646.000	98.725, 7630.840	98.725, 7630.840	0.000, 173.712	0.000, 0.000	0.000, 50.920
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1701.630, 724.950	1701.630, 724.950	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	2323.5700, 1341.5100	2323.5700, 1341.5100	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	582.232	582.232	0.000	NA	0.000
	MIN, MAX	NA, NA	149.640, 4373.005	149.640, 4373.005	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	149.640, 4373.010	149.640, 4373.010	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2646.910, 2646.910	2646.910, 2646.910	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	2646.910	2646.910	0.000	0.000	0.000
	MIN, MAX	NA, NA	2646.905, 2646.905	2646.905, 2646.905	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	26	33	59
	MEAN, GEO MEAN	2636.820, NA	3588.440, 2227.360	3203.260, NA	3.610, NA	10.781, NA	7.621, NA
	SD, SE	2140.5700, 519.1640	3331.0100, 666.2010	2916.6100, 450.0420	10.6659, 2.0918	39.9647, 6.9570	30.7104, 3.9982
	MEDIAN	1703.200	2889.060	2518.300	0.000	0.000	0.000
	MIN, MAX	0.000, 7252.530	20.460, 17356.612	0.000, 17356.612	0.000, 40.950	0.000, 168.831	0.000, 168.831
	5%, 95%	0.000, 7252.530	65.136, 6821.100	65.136, 6821.100	0.000, 36.120	0.000, 160.433	0.000, 40.950
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	892.241, 669.116	892.241, 669.116	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	852.2710, 492.0590	852.2710, 492.0590	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	425.304	425.304	0.000	NA	0.000
	MIN, MAX	NA, NA	375.480, 1875.938	375.480, 1875.938	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	375.480, 1875.940	375.480, 1875.940	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2632.190, 2632.190	2632.190, 2632.190	7.200, 7.200	0.000, NA	2.400, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	4.1569, 2.4000
	MEDIAN	NA	2632.190	2632.190	7.200	0.000	0.000
	MIN, MAX	NA, NA	2632.190, 2632.190	2632.190, 2632.190	7.200, 7.200	0.000, 0.000	0.000, 7.200
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 7.200
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2839.650, NA	3191.710, 2143.170	3053.950, NA	21.223, NA	5.462, NA	12.697, NA
	SD, SE	2316.2800, 545.9520	2312.8400, 437.0860	2294.9000, 338.3640	81.0176, 15.3109	19.9668, 3.4758	56.8250, 7.2757
	MEDIAN	2120.440	2703.380	2644.190	0.000	0.000	0.000
	MIN, MAX	0.000, 7949.270	58.188, 10073.400	0.000, 10073.400	0.000, 420.910	0.000, 84.416	0.000, 420.910
	5%, 95%	0.000, 7949.270	59.593, 7804.880	59.593, 7804.880	0.000, 107.331	0.000, 80.217	0.000, 80.217
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1296.930, 744.867	1296.930, 744.867	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	1587.2800, 916.4180	1587.2800, 916.4180	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	503.768	503.768	0.000	NA	0.000
	MIN, MAX	NA, NA	262.560, 3124.470	262.560, 3124.470	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	262.560, 3124.470	262.560, 3124.470	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.789, 1.789	1.789, 1.789	0.006, 0.006	0.000, NA	0.002, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0035, 0.0020
	MEDIAN	NA	1.789	1.789	0.006	0.000	0.000
	MIN, MAX	NA, NA	1.789, 1.789	1.789, 1.789	0.006, 0.006	0.000, 0.000	0.000, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.006
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	28	45	27	30	57
	MEAN, GEO MEAN	2.232, NA	2.783, 1.842	2.575, NA	0.028, NA	0.000, NA	0.014, NA
	SD, SE	2.1168, 0.5134	2.0310, 0.3838	2.0576, 0.3067	0.1208, 0.0233	0.0005, 0.0001	0.0836, 0.0111
	MEDIAN	1.190	2.289	2.284	0.000	0.000	0.000
	MIN, MAX	0.000, 8.643	0.027, 7.951	0.000, 8.643	0.000, 0.624	0.000, 0.003	0.000, 0.624
	5%, 95%	0.000, 8.643	0.082, 7.656	0.082, 7.656	0.000, 0.107	0.000, 0.000	0.000, 0.024
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.054, 0.512	1.054, 0.512	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	1.3891, 0.8020	1.3891, 0.8020	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.375	0.375	0.000	NA	0.000
	MIN, MAX	NA, NA	0.135, 2.652	0.135, 2.652	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.135, 2.652	0.135, 2.652	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537719

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 140 of ?)

Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.594, 1.594	1.594, 1.594	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	1.594	1.594	0.000	0.000	0.000
	MIN, MAX	NA, NA	1.594, 1.594	1.594, 1.594	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	26	33	59
	MEAN, GEO MEAN	1.818, NA	2.887, 1.832	2.454, NA	0.002, NA	0.010, NA	0.006, NA
	SD, SE	1.3733, 0.3331	2.2552, 0.4510	1.9989, 0.3084	0.0058, 0.0011	0.0369, 0.0064	0.0280, 0.0036
	MEDIAN	1.355	1.990	1.846	0.000	0.000	0.000
	MIN, MAX	0.000, 4.312	0.020, 9.761	0.000, 9.761	0.000, 0.023	0.000, 0.171	0.000, 0.171
	5%, 95%	0.000, 4.312	0.043, 6.968	0.043, 6.216	0.000, 0.019	0.000, 0.131	0.000, 0.023
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.389, 0.860	1.389, 0.860	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	1.6446, 0.9495	1.6446, 0.9495	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.442	0.442	0.000	NA	0.000
	MIN, MAX	NA, NA	0.437, 3.288	0.437, 3.288	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.437, 3.288	0.437, 3.288	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537720

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 141 of ?)

Lab: Madison
Biomarker: NNAL-Glucuronide (pmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.692, 1.692	1.692, 1.692	0.003, 0.003	0.000, NA	0.001, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0017, 0.0010
	MEDIAN	NA	1.692	1.692	0.003	0.000	0.000
	MIN, MAX	NA, NA	1.692, 1.692	1.692, 1.692	0.003, 0.003	0.000, 0.000	0.000, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.003
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2.037, NA	2.800, 1.858	2.502, NA	0.015, NA	0.005, NA	0.009, NA
	SD, SE	1.6980, 0.4002	1.9748, 0.3732	1.8897, 0.2786	0.0596, 0.0113	0.0186, 0.0032	0.0425, 0.0054
	MEDIAN	1.169	2.068	1.996	0.000	0.000	0.000
	MIN, MAX	0.000, 6.478	0.035, 7.312	0.000, 7.312	0.000, 0.312	0.000, 0.086	0.000, 0.312
	5%, 95%	0.000, 6.478	0.051, 7.084	0.051, 6.478	0.000, 0.065	0.000, 0.066	0.000, 0.065
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1.222, 0.704	1.222, 0.704	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	1.5152, 0.8748	1.5152, 0.8748	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.406	0.406	0.000	NA	0.000
	MIN, MAX	NA, NA	0.289, 2.970	0.289, 2.970	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.289, 2.970	0.289, 2.970	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537721

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 142 of 7)

Lab: INBIFO
Biomarker: Total Nicotine (umol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	38.100, 38.100	NA, NA	38.100, 38.100
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	38.100	NA	38.100
	MIN, MAX	NA, NA	NA, NA	NA, NA	38.100, 38.100	NA, NA	38.100, 38.100
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	18044.400, 14878.500	8635.730, 8049.120	13340.100, 10943.400	NA, NA	27.991, 24.918	27.991, 24.918
	SD, SE	10825.2000, 6249.9100	4082.2800, 2356.9000	8949.6800, 3653.6900	NA, NA	18.0326, 12.7510	18.0326, 12.7510
	MEDIAN	23200.400	7159.230	10205.000	NA	27.991	27.991
	MIN, MAX	5605.104, 25327.788	5497.128, 13250.825	5497.128, 25327.788	NA, NA	15.240, 40.742	15.240, 40.742
	5%, 95%	5605.100, 25327.800	5497.130, 13250.800	5497.130, 25327.800	NA, NA	15.240, 40.742	15.240, 40.742
	BLQ Values Included	0	0	0	NA	2	2

PM3003537722

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 143 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	34.925, 34.925	NA, NA	34.925, 34.925
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	34.925	NA	34.925
	MIN, MAX	NA, NA	NA, NA	NA, NA	34.925, 34.925	NA, NA	34.925, 34.925
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	3	4
	MEAN, GEO MEAN	13631.100, 12261.200	11106.900, 10275.600	12369.000, 11224.600	36.830, 36.830	43.690, 43.268	41.975, 41.560
	SD, SE	6848.8600, 3954.1900	5507.4000, 3179.7000	5727.7200, 2338.3300	NA, NA	7.4446, 4.2981	6.9794, 3.4897
	MEDIAN	14725.700	9159.570	11942.600	36.830	43.180	40.005
	MIN, MAX	6300.791, 19866.660	6837.732, 17323.410	6300.791, 19866.660	36.830, 36.830	36.513, 51.376	36.513, 51.376
	5%, 95%	6300.790, 19866.700	6837.730, 17323.400	6300.790, 19866.700	NA, NA	36.513, 51.376	36.513, 51.376
	BLQ Values Included	0	0	0	1	2	3

PM3003537723

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	36.957, 36.957	NA, NA	36.957, 36.957
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	36.957	NA	36.957
	MIN, MAX	NA, NA	NA, NA	NA, NA	36.957, 36.957	NA, NA	36.957, 36.957
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	8440.240, 6209.580	10011.500, 9589.060	9383.020, 8059.170	28.634, 28.050	26.839, 24.948	27.737, 26.453
	SD, SE	8084.4000, 5716.5300	3639.1700, 2101.0800	4868.4500, 2177.2400	7.2930, 4.2106	12.5835, 7.2651	9.2509, 3.7767
	MEDIAN	8440.240	9143.680	9143.680	26.213	23.876	25.045
	MIN, MAX	2723.706, 14156.770	6884.745, 14006.175	2723.706, 14156.770	22.860, 36.830	16.002, 40.640	16.002, 40.640
	5%, 95%	2723.710, 14156.800	6884.750, 14006.200	2723.710, 14156.800	22.860, 36.830	16.002, 40.640	16.002, 40.640
	BLQ Values Included	0	0	0	3	3	6

PM3003537724

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	36.661, 36.661	NA, NA	36.661, 36.661
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	36.661	NA	36.661
	MIN, MAX	NA, NA	NA, NA	NA, NA	36.661, 36.661	NA, NA	36.661, 36.661
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	14541.100, 12230.500	9918.040, 9370.860	12229.600, 10705.600	28.634, 28.050	33.455, 33.106	31.045, 30.473
	SD, SE	8379.8200, 4838.0900	4289.5900, 2476.6000	6469.9800, 2641.3600	7.2930, 4.2106	5.8798, 3.3947	6.4866, 2.6481
	MEDIAN	18963.100	7734.520	11297.300	26.213	33.528	30.534
	MIN, MAX	4876.530, 19783.700	7159.510, 14860.100	4876.530, 19783.700	22.860, 36.830	27.539, 39.298	22.860, 39.298
	5%, 95%	4876.530, 19783.700	7159.510, 14860.100	4876.530, 19783.700	22.860, 36.830	27.539, 39.298	22.860, 39.298

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537725

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 146 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	6.180, 6.180	NA, NA	6.180, 6.180
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	6.180	NA	6.180
	MIN, MAX	NA, NA	NA, NA	NA, NA	6.180, 6.180	NA, NA	6.180, 6.180
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	2926.810, 2413.290	1400.720, 1305.570	2163.760, 1775.030	NA, NA	4.540, 4.042	4.540, 4.042
	SD, SE	1755.8400, 1013.7400	662.1460, 382.2900	1451.6400, 592.6290	NA, NA	2.9246, 2.0680	2.9246, 2.0680
	MEDIAN	3763.110	1161.230	1655.260	NA	4.540	4.540
	MIN, MAX	909.148, 4108.167	891.634, 2149.284	891.634, 4108.167	NA, NA	2.472, 6.608	2.472, 6.608
	5%, 95%	909.148, 4108.170	891.634, 2149.280	891.634, 4108.170	NA, NA	2.472, 6.608	2.472, 6.608
	BLQ Values Included	0	0	0	NA	2	2

PM3003537726

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 147 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.665, 5.665	NA, NA	5.665, 5.665
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.665	NA	5.665
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.665, 5.665	NA, NA	5.665, 5.665
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	3	4
	MEAN, GEO MEAN	2210.960, 1988.760	1801.540, 1666.700	2006.250, 1820.620	5.974, 5.974	7.086, 7.018	6.808, 6.741
	SD, SE	1110.8900, 641.3700	893.3000, 515.7470	929.0360, 379.2770	NA, NA	1.2076, 0.6972	1.1320, 0.5660
	MEDIAN	2388.510	1485.680	1937.100	5.974	7.004	6.489
	MIN, MAX	1021.988, 3222.372	1109.080, 2809.857	1021.988, 3222.372	5.974, 5.974	5.922, 8.333	5.922, 8.333
	5%, 95%	1021.990, 3222.370	1109.080, 2809.860	1021.990, 3222.370	NA, NA	5.922, 8.333	5.922, 8.333
	BLQ Values Included	0	0	0	1	2	3

PM3003537727

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.994, 5.994	NA, NA	5.994, 5.994
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.994	NA	5.994
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.994, 5.994	NA, NA	5.994, 5.994
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	1369.010, 1007.190	1623.870, 1555.350	1521.930, 1307.200	4.645, 4.550	4.354, 4.047	4.499, 4.291
	SD, SE	1311.2900, 927.2220	590.2740, 340.7950	789.6630, 353.1480	1.1829, 0.6830	2.0409, 1.1783	1.5004, 0.6125
	MEDIAN	1369.010	1483.110	1483.110	4.252	3.873	4.063
	MIN, MAX	441.785, 2296.228	1116.706, 2271.802	441.785, 2296.228	3.708, 5.974	2.596, 6.592	2.596, 6.592
	5%, 95%	441.785, 2296.230	1116.710, 2271.800	441.785, 2296.230	3.708, 5.974	2.596, 6.592	2.596, 6.592
	BLQ Values Included	0	0	0	3	3	6

PM3003537728

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 149 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.946, 5.946	NA, NA	5.946, 5.946
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.946	NA	5.946
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.946, 5.946	NA, NA	5.946, 5.946
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	2358.570, 1983.780	1608.710, 1519.950	1983.640, 1736.450	4.645, 4.550	5.427, 5.370	5.036, 4.943
	SD, SE	1359.2100, 784.7380	695.7730, 401.7050	1049.4300, 428.4280	1.1829, 0.6830	0.9536, 0.5505	1.0521, 0.4295
	MEDIAN	3075.810	1254.540	1832.430	4.252	5.439	4.953
	MIN, MAX	790.974, 3208.920	1161.270, 2410.310	790.974, 3208.920	3.708, 5.974	4.467, 6.374	3.708, 6.374
	5%, 95%	790.974, 3208.920	1161.270, 2410.310	790.974, 3208.920	3.708, 5.974	4.467, 6.374	3.708, 6.374

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537729

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	10.200, 10.200	NA, NA	10.200, 10.200
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	10.200	NA	10.200
	MIN, MAX	NA, NA	NA, NA	NA, NA	10.200, 10.200	NA, NA	10.200, 10.200
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	14331.700, 12198.500	4905.960, 4586.580	9618.830, 7479.920	6.936, 6.936	4.080, 4.080	5.508, 5.320
	SD, SE	8085.8500, 4568.3700	2292.4100, 1323.5200	7409.9900, 3025.1100	NA, NA	NA, NA	2.0195, 1.4280
	MEDIAN	18042.800	3934.140	6290.340	6.936	4.080	5.508
	MIN, MAX	5056.480, 19895.897	3259.536, 7524.195	3259.536, 19895.897	6.936, 6.936	4.080, 4.080	4.080, 6.936
	5%, 95%	5056.480, 19895.900	3259.540, 7524.200	3259.540, 19895.900	NA, NA	NA, NA	4.080, 6.936
	BLQ Values Included	0	0	0	1	1	2

PM3003537730

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	9324.810, 8030.610	7091.660, 6235.020	8208.240, 7076.090	NA, NA	7.548, 6.393	7.548, 6.393
	SD, SE	5185.5600, 2993.8900	4448.8200, 2568.5300	4490.9800, 1833.4400	NA, NA	5.6738, 4.0120	5.6738, 4.0120
	MEDIAN	11101.500	5608.210	8354.880	NA	7.548	7.548
	MIN, MAX	3484.431, 13388.466	3574.098, 12092.675	3484.431, 13388.466	NA, NA	3.536, 11.560	3.536, 11.560
	5%, 95%	3484.430, 13388.500	3574.100, 12092.700	3484.430, 13388.500	NA, NA	3.536, 11.560	3.536, 11.560
	BLQ Values Included	0	0	0	NA	2	2

PM3003537731

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	5166.300, 4177.410	6564.500, 6173.720	6005.220, 5280.690	6.569, 6.554	7.582, 6.827	7.076, 6.689
	SD, SE	4298.8100, 3039.7200	2592.1300, 1496.5700	2926.7700, 1308.8900	0.6350, 0.4490	4.6641, 3.2980	2.7799, 1.3899
	MEDIAN	5166.300	7103.310	7103.310	6.569	7.582	6.569
	MIN, MAX	2126.580, 8206.010	3745.315, 8844.885	2126.580, 8844.885	6.120, 7.018	4.284, 10.880	4.284, 10.880
	5%, 95%	2126.580, 8206.010	3745.320, 8844.890	2126.580, 8844.890	6.120, 7.018	4.284, 10.880	4.284, 10.880
	BLQ Values Included	0	0	0	2	2	4

PM3003537732

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	10.200, 10.200	NA, NA	10.200, 10.200
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	10.200	NA	10.200
	MIN, MAX	NA, NA	NA, NA	NA, NA	10.200, 10.200	NA, NA	10.200, 10.200
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	10755.600, 8996.480	6187.370, 5801.020	8471.510, 7224.180	6.773, 6.769	8.802, 7.931	7.991, 7.444
	SD, SE	6339.1500, 3659.9100	2859.8300, 1651.1200	5060.2400, 2065.8400	0.3465, 0.2450	4.2013, 2.4256	3.1766, 1.4206
	MEDIAN	13212.400	4645.650	7066.450	6.773	10.880	7.018
	MIN, MAX	3555.830, 15498.700	4429.220, 9487.250	3555.830, 15498.700	6.528, 7.018	3.967, 11.560	3.967, 11.560
	5%, 95%	3555.830, 15498.700	4429.220, 9487.250	3555.830, 15498.700	6.528, 7.018	3.967, 11.560	3.967, 11.560

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537733

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 154 of 7)

Lab: INBIFO
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.654, 1.654	NA, NA	1.654, 1.654
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.654	NA	1.654
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.654, 1.654	NA, NA	1.654, 1.654
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	2324.600, 1978.590	795.746, 743.943	1560.170, 1213.240	1.125, 1.125	0.662, 0.662	0.894, 0.863
	SD, SE	1311.5200, 757.2090	371.8290, 214.6750	1201.9000, 490.6730	NA, NA	NA, NA	0.3274, 0.2315
	MEDIAN	2926.540	638.118	1020.290	1.125	0.662	0.894
	MIN, MAX	820.161, 3227.114	528.697, 1220.424	528.697, 3227.114	1.125, 1.125	0.662, 0.662	0.662, 1.125
	5%, 95%	820.161, 3227.110	528.697, 1220.420	528.697, 3227.110	NA, NA	NA, NA	0.662, 1.125
	BLQ Values Included	0	0	0	1	1	2

PM3003537734

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 155 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	1512.490, 1302.570	1150.270, 1011.320	1331.380, 1147.740	NA, NA	1.225, 1.037	1.225, 1.037
	SD, SE	841.0980, 485.6080	721.5990, 416.6150	728.4370, 297.3830	NA, NA	0.9199, 0.6505	0.9199, 0.6505
	MEDIAN	1800.670	909.652	1355.160	NA	1.225	1.225
	MIN, MAX	565.175, 2171.609	579.719, 1961.432	565.175, 2171.609	NA, NA	0.574, 1.875	0.574, 1.875
	5%, 95%	565.175, 2171.610	579.719, 1961.430	565.175, 2171.610	NA, NA	0.574, 1.875	0.574, 1.875
	BLQ Values Included	0	0	0	NA	2	2

PM3003537735

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 156 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	837.973, 677.575	1064.760, 1001.380	974.047, 856.528	1.066, 1.063	1.230, 1.108	1.148, 1.085
	SD, SE	697.2670, 493.0420	420.4430, 242.7430	474.7230, 212.3020	0.1025, 0.0725	0.7566, 0.5350	0.4509, 0.2255
	MEDIAN	837.973	1152.160	1152.160	1.066	1.230	1.066
	MIN, MAX	344.931, 1331.015	607.490, 1434.640	344.931, 1434.640	0.993, 1.138	0.695, 1.765	0.695, 1.765
	5%, 95%	344.931, 1331.020	607.490, 1434.640	344.931, 1434.640	0.993, 1.138	0.695, 1.765	0.695, 1.765
	BLQ Values Included	0	0	0	2	2	4

PM3003537736

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 157 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.654, 1.654	NA, NA	1.654, 1.654
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.654	NA	1.654
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.654, 1.654	NA, NA	1.654, 1.654
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	1744.570, 1459.230	1003.590, 940.926	1374.080, 1171.760	1.099, 1.098	1.428, 1.287	1.296, 1.208
	SD, SE	1028.2100, 593.6370	463.8620, 267.8110	820.7720, 335.0790	0.0559, 0.0395	0.6812, 0.3933	0.5151, 0.2304
	MEDIAN	2143.050	753.524	1146.180	1.099	1.765	1.138
	MIN, MAX	576.756, 2513.890	718.420, 1538.830	576.756, 2513.890	1.059, 1.138	0.644, 1.875	0.644, 1.875
	5%, 95%	576.756, 2513.890	718.420, 1538.830	576.756, 2513.890	1.059, 1.138	0.644, 1.875	0.644, 1.875

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537737

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	33.000, 33.000	NA, NA	33.000, 33.000
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	33.000	NA	33.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	33.000, 33.000	NA, NA	33.000, 33.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	20519.900, 14594.600	22557.700, 21545.600	21538.800, 17732.700	17.783, 17.484	24.244, 21.582	20.368, 19.021
	SD, SE	15520.1000, 8960.5200	8433.2900, 4868.9600	11226.9000, 4583.3600	4.1163, 2.3766	15.6186, 11.0440	9.0542, 4.0492
	MEDIAN	23030.200	20668.900	21849.600	16.280	24.244	16.280
	MIN, MAX	3897.624, 34631.742	15229.032, 31775.275	3897.624, 34631.742	14.630, 22.440	13.200, 35.288	13.200, 35.288
	5%, 95%	3897.620, 34631.700	15229.000, 31775.300	3897.620, 34631.700	14.630, 22.440	13.200, 35.288	13.200, 35.288
	BLQ Values Included	0	0	0	3	2	5

PM3003537738

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	30.250, 30.250	NA, NA	30.250, 30.250
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	30.250	NA	30.250
	MIN, MAX	NA, NA	NA, NA	NA, NA	30.250, 30.250	NA, NA	30.250, 30.250
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	19603.500, 16623.700	24282.000, 23633.000	21942.800, 19820.900	22.953, 22.168	26.822, 23.829	24.888, 22.984
	SD, SE	11343.8000, 6549.3200	6492.9000, 3748.6800	8654.6000, 3533.2300	7.7480, 4.4733	13.6303, 7.8694	10.1398, 4.1396
	MEDIAN	23209.000	26974.000	25091.500	18.480	31.625	25.053
	MIN, MAX	6895.195, 28706.310	16876.134, 28995.975	6895.195, 28995.975	18.480, 31.900	11.440, 37.400	11.440, 37.400
	5%, 95%	6895.200, 28706.300	16876.100, 28996.000	6895.200, 28996.000	18.480, 31.900	11.440, 37.400	11.440, 37.400
	BLQ Values Included	0	0	0	3	3	6

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001
PM3003537739

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 160 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	32.010, 32.010	NA, NA	32.010, 32.010
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	32.010	NA	32.010
	MIN, MAX	NA, NA	NA, NA	NA, NA	32.010, 32.010	NA, NA	32.010, 32.010
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	16931.500, 8752.580	19312.100, 18375.600	18359.900, 13658.400	24.801, 24.295	16.903, 16.673	20.852, 20.126
	SD, SE	20497.3000, 14493.8000	6996.5000, 4039.4300	11454.7000, 5122.7000	6.3168, 3.6470	3.4686, 2.0026	6.2838, 2.5654
	MEDIAN	16931.500	20410.500	20410.500	22.704	16.170	20.240
	MIN, MAX	2437.770, 31425.320	11831.363, 25694.435	2437.770, 31425.320	19.800, 31.900	13.860, 20.680	13.860, 31.900
	5%, 95%	2437.770, 31425.300	11831.400, 25694.400	2437.770, 31425.300	19.800, 31.900	13.860, 20.680	13.860, 31.900
	BLQ Values Included	0	0	0	3	3	6

PM3003537740

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	31.753, 31.753	NA, NA	31.753, 31.753
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	31.753	NA	31.753
	MIN, MAX	NA, NA	NA, NA	NA, NA	31.753, 31.753	NA, NA	31.753, 31.753
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	19705.900, 14767.900	22050.600, 21235.000	20878.300, 17708.700	21.846, 21.581	22.875, 21.190	22.434, 21.357
	SD, SE	13906.7000, 8029.0200	7109.4200, 4104.6300	9961.1900, 4066.6400	4.2765, 2.4690	9.9295, 4.9647	7.4630, 2.8207
	MEDIAN	23119.600	22684.500	22902.100	20.240	22.605	20.240
	MIN, MAX	4410.200, 31587.800	14645.500, 28821.900	4410.200, 31587.800	18.605, 26.693	12.833, 33.457	12.833, 33.457
	5%, 95%	4410.200, 31587.800	14645.500, 28821.900	4410.200, 31587.800	18.605, 26.693	12.833, 33.457	12.833, 33.457

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537741

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.815, 5.815	NA, NA	5.815, 5.815
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.815	NA	5.815
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.815, 5.815	NA, NA	5.815, 5.815
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	3615.600, 2571.560	3974.670, 3796.340	3795.140, 3124.500	3.134, 3.081	4.272, 3.803	3.589, 3.352
	SD, SE	2734.6400, 1578.8400	1485.9500, 857.9110	1978.1800, 807.5880	0.7252, 0.4187	2.7521, 1.9460	1.5953, 0.7135
	MEDIAN	4057.930	3641.860	3849.890	2.869	4.272	2.869
	MIN, MAX	686.761, 6102.113	2683.355, 5598.803	686.761, 6102.113	2.578, 3.954	2.326, 6.218	2.326, 6.218
	5%, 95%	686.761, 6102.110	2683.360, 5598.800	686.761, 6102.110	2.578, 3.954	2.326, 6.218	2.326, 6.218
	BLQ Values Included	0	0	0	3	2	5

PM3003537742

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 163 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.330, 5.330	NA, NA	5.330, 5.330
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.330	NA	5.330
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.330, 5.330	NA, NA	5.330, 5.330
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3454.140, 2929.090	4278.500, 4164.130	3866.320, 3492.440	4.044, 3.906	4.726, 4.199	4.385, 4.050
	SD, SE	1998.7700, 1153.9900	1144.0500, 660.5170	1524.9400, 622.5540	1.3654, 0.7883	2.4015, 1.3865	1.7866, 0.7294
	MEDIAN	4089.420	4752.820	4421.120	3.256	5.572	4.414
	MIN, MAX	1214.933, 5058.052	2973.575, 5109.091	1214.933, 5109.091	3.256, 5.621	2.016, 6.590	2.016, 6.590
	5%, 95%	1214.930, 5058.050	2973.580, 5109.090	1214.930, 5109.090	3.256, 5.621	2.016, 6.590	2.016, 6.590
	BLQ Values Included	0	0	0	3	3	6

PM3003537743

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.640, 5.640	NA, NA	5.640, 5.640
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.640	NA	5.640
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.640, 5.640	NA, NA	5.640, 5.640
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	2983.340, 1542.200	3402.790, 3237.790	3235.010, 2406.610	4.370, 4.281	2.978, 2.938	3.674, 3.546
	SD, SE	3611.6200, 2553.8000	1232.7800, 711.7480	2018.3200, 902.6200	1.1131, 0.6427	0.6113, 0.3530	1.1073, 0.4521
	MEDIAN	2983.340	3596.320	3596.320	4.000	2.849	3.567
	MIN, MAX	429.535, 5537.141	2084.686, 4527.359	429.535, 5537.141	3.489, 5.621	2.442, 3.644	2.442, 5.621
	5%, 95%	429.535, 5537.140	2084.690, 4527.360	429.535, 5537.140	3.489, 5.621	2.442, 3.644	2.442, 5.621
	BLQ Values Included	0	0	0	3	3	6

PM3003537744

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	5.595, 5.595	NA, NA	5.595, 5.595
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	5.595	NA	5.595
	MIN, MAX	NA, NA	NA, NA	NA, NA	5.595, 5.595	NA, NA	5.595, 5.595
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3472.180, 2602.110	3885.320, 3741.600	3678.750, 3120.270	3.849, 3.803	4.031, 3.734	3.953, 3.763
	SD, SE	2450.3600, 1414.7100	1252.6800, 723.2350	1755.1600, 716.5410	0.7540, 0.4353	1.7497, 0.8748	1.3151, 0.4971
	MEDIAN	4073.680	3997.000	4035.340	3.566	3.983	3.566
	MIN, MAX	777.076, 5565.770	2580.540, 5078.420	777.076, 5565.770	3.278, 4.704	2.261, 5.895	2.261, 5.895
	5%, 95%	777.076, 5565.770	2580.540, 5078.420	777.076, 5565.770	3.278, 4.704	2.261, 5.895	2.261, 5.895

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537745

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	9.300, 9.300	NA, NA	9.300, 9.300
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	9.300	NA	9.300
	MIN, MAX	NA, NA	NA, NA	NA, NA	9.300, 9.300	NA, NA	9.300, 9.300
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	7447.930, 6580.250	8784.550, 8271.040	8116.240, 7377.370	12.903, 9.308	6.909, 6.393	9.906, 7.714
	SD, SE	3854.3400, 2225.3100	3413.1500, 1970.5800	3337.3900, 1362.4800	12.9278, 7.4638	3.1153, 1.7986	9.0284, 3.6858
	MEDIAN	8796.400	9681.650	9239.020	6.324	7.062	6.693
	MIN, MAX	3100.528, 10446.873	5012.448, 11659.550	3100.528, 11659.550	4.588, 27.797	3.720, 9.945	3.720, 27.797
	5%, 95%	3100.530, 10446.900	5012.450, 11659.600	3100.530, 11659.600	4.588, 27.797	3.720, 9.945	3.720, 27.797
	BLQ Values Included	0	0	0	2	3	5

PM3003537746

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 167 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	8.525, 8.525	NA, NA	8.525, 8.525
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	8.525	NA	8.525
	MIN, MAX	NA, NA	NA, NA	NA, NA	8.525, 8.525	NA, NA	8.525, 8.525
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	6966.870, 6705.080	10347.600, 9953.410	8657.220, 8169.360	6.469, 6.247	7.374, 6.742	6.986, 6.525
	SD, SE	2243.0800, 1295.0400	3472.8300, 2005.0400	3203.9800, 1308.0200	2.1835, 1.2607	3.1581, 1.5791	2.6097, 0.9864
	MEDIAN	7302.800	10102.000	8162.920	5.208	7.867	6.820
	MIN, MAX	4574.775, 9023.046	7004.052, 13936.670	4574.775, 13936.670	5.208, 8.990	3.224, 10.540	3.224, 10.540
	5%, 95%	4574.780, 9023.050	7004.050, 13936.700	4574.780, 13936.700	5.208, 8.990	3.224, 10.540	3.224, 10.540
	BLQ Values Included	0	0	0	3	4	7

PM3003537747

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	4	7
	MEAN, GEO MEAN	7079.080, 5030.830	7500.510, 7079.280	7331.940, 6175.170	6.989, 6.847	6.053, 5.664	6.454, 6.143
	SD, SE	7043.3200, 4980.3800	2979.9000, 1720.4500	4110.3900, 1838.2200	1.7802, 1.0278	2.6989, 1.3494	2.2246, 0.8408
	MEDIAN	7079.080	7564.870	7564.870	6.398	5.193	5.828
	MIN, MAX	2098.704, 12059.465	4488.944, 10447.710	2098.704, 12059.465	5.580, 8.990	3.906, 9.920	3.906, 9.920
	5%, 95%	2098.700, 12059.500	4488.940, 10447.700	2098.700, 12059.500	5.580, 8.990	3.906, 9.920	3.906, 9.920
	BLQ Values Included	0	0	0	3	4	7

PM3003537748

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 169 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	8.913, 8.913	NA, NA	8.913, 8.913
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	8.913	NA	8.913
	MIN, MAX	NA, NA	NA, NA	NA, NA	8.913, 8.913	NA, NA	8.913, 8.913
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	7272.470, 6507.890	8877.540, 8499.390	8075.000, 7437.280	8.787, 8.260	6.885, 6.463	7.700, 7.180
	SD, SE	3687.8300, 2129.1700	2928.4600, 1690.7500	3105.3600, 1267.7600	3.8729, 2.2360	2.5979, 1.2989	3.0672, 1.1593
	MEDIAN	8049.600	10394.400	9222.000	7.523	7.165	7.523
	MIN, MAX	3258.000, 10509.800	5501.810, 10736.400	3258.000, 10736.400	5.704, 13.134	3.617, 9.593	3.617, 13.134
	5%, 95%	3258.000, 10509.800	5501.810, 10736.400	3258.000, 10736.400	5.704, 13.134	3.617, 9.593	3.617, 13.134

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537749

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 170 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.639, 1.639	NA, NA	1.639, 1.639
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.639	NA	1.639
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.639, 1.639	NA, NA	1.639, 1.639
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	1312.330, 1159.440	1547.840, 1457.360	1430.080, 1299.890	2.273, 1.640	1.217, 1.126	1.745, 1.359
	SD, SE	679.1350, 392.0990	601.3970, 347.2170	588.0490, 240.0700	2.2782, 1.3153	0.5490, 0.3170	1.5910, 0.6495
	MEDIAN	1549.930	1705.910	1627.920	1.114	1.244	1.179
	MIN, MAX	546.313, 1840.739	883.193, 2054.413	546.313, 2054.413	0.808, 4.898	0.655, 1.752	0.655, 4.898
	5%, 95%	546.313, 1840.740	883.193, 2054.410	546.313, 2054.410	0.808, 4.898	0.655, 1.752	0.655, 4.898
	BLQ Values Included	0	0	0	2	3	5

PM3003537750

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.502, 1.502	NA, NA	1.502, 1.502
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.502	NA	1.502
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.502, 1.502	NA, NA	1.502, 1.502
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	1227.560, 1181.440	1823.240, 1753.790	1525.400, 1439.440	1.140, 1.101	1.299, 1.188	1.231, 1.150
	SD, SE	395.2310, 228.1870	611.9120, 353.2880	564.5420, 230.4730	0.3845, 0.2220	0.5563, 0.2782	0.4597, 0.1737
	MEDIAN	1286.750	1779.970	1438.310	0.918	1.386	1.202
	MIN, MAX	806.075, 1589.861	1234.114, 2455.641	806.075, 2455.641	0.918, 1.584	0.568, 1.857	0.568, 1.857
	5%, 95%	806.075, 1589.860	1234.110, 2455.640	806.075, 2455.640	0.918, 1.584	0.568, 1.857	0.568, 1.857
	BLQ Values Included	0	0	0	3	4	7

PM3003537751

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 172 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	4	7
	MEAN, GEO MEAN	1247.340, 886.433	1321.590, 1247.370	1291.890, 1088.070	1.231, 1.206	1.067, 0.998	1.137, 1.082
	SD, SE	1241.0300, 877.5430	525.0590, 303.1430	724.2500, 323.8950	0.3138, 0.1812	0.4756, 0.2378	0.3920, 0.1482
	MEDIAN	1247.340	1332.930	1332.930	1.127	0.915	1.027
	MIN, MAX	369.792, 2124.878	790.952, 1840.887	369.792, 2124.878	0.983, 1.584	0.688, 1.748	0.688, 1.748
	5%, 95%	369.792, 2124.880	790.952, 1840.890	369.792, 2124.880	0.983, 1.584	0.688, 1.748	0.688, 1.748
	BLQ Values Included	0	0	0	3	4	7

PM3003537752

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 173 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.571, 1.571	NA, NA	1.571, 1.571
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.571	NA	1.571
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.571, 1.571	NA, NA	1.571, 1.571
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	1281.410, 1146.690	1564.220, 1497.590	1422.820, 1310.450	1.548, 1.455	1.213, 1.139	1.357, 1.265
	SD, SE	649.7970, 375.1610	515.9960, 297.9100	547.1660, 223.3790	0.6824, 0.3940	0.4578, 0.2289	0.5404, 0.2043
	MEDIAN	1418.340	1831.490	1624.920	1.325	1.263	1.325
	MIN, MAX	574.060, 1851.830	969.420, 1891.760	574.060, 1891.760	1.005, 2.314	0.637, 1.690	0.637, 2.314
	5%, 95%	574.060, 1851.830	969.420, 1891.760	574.060, 1891.760	1.005, 2.314	0.637, 1.690	0.637, 2.314

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537753

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 174 of 7)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	24791.600, 21723.300	41612.400, 39914.900	33202.000, 29446.300	42.241, 38.693	62.528, 42.850	54.413, 41.136
	SD, SE	15099.3000, 8717.5600	15356.3000, 8865.9600	16444.0000, 6713.2200	23.9631, 16.9445	62.2237, 35.9249	46.9354, 20.9901
	MEDIAN	21746.200	34072.600	32778.000	42.241	39.779	39.779
	MIN, MAX	11447.120, 41181.385	31483.480, 59281.220	11447.120, 59281.220	25.296, 59.185	14.880, 132.925	14.880, 132.925
	5%, 95%	11447.100, 41181.400	31483.500, 59281.200	11447.100, 59281.200	25.296, 59.185	14.880, 132.925	14.880, 132.925
	BLQ Values Included	0	0	0	1	2	3

PM3003537754

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 175 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	24166.900, 21982.600	45347.300, 39977.300	34757.100, 29644.700	42.395, 37.499	24.273, 21.442	35.146, 29.986
	SD, SE	13076.3000, 7549.6200	28769.8000, 16610.2000	23109.7000, 9434.5000	25.3989, 14.6640	16.0895, 11.3770	22.0406, 9.8569
	MEDIAN	19995.700	33423.900	28940.000	35.960	24.273	35.650
	MIN, MAX	13685.048, 38819.979	24456.168, 78161.850	13685.048, 78161.850	20.832, 70.392	12.896, 35.650	12.896, 70.392
	5%, 95%	13685.000, 38820.000	24456.200, 78161.900	13685.000, 78161.900	20.832, 70.392	12.896, 35.650	12.896, 70.392
	BLQ Values Included	0	0	0	2	2	4

PM3003537755

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	2	5
	MEAN, GEO MEAN	14960.900, 11909.700	33116.000, 25344.500	25853.900, 18736.600	27.958, 27.387	27.652, 24.899	27.836, 26.364
	SD, SE	12805.2000, 9054.6400	30639.5000, 17689.7000	24683.3000, 11038.7000	7.1207, 4.1111	17.0102, 12.0280	9.8852, 4.4208
	MEDIAN	14960.900	16042.200	16042.200	25.594	27.652	25.594
	MIN, MAX	5906.262, 24015.545	14817.346, 68488.280	5906.262, 68488.280	22.320, 35.960	15.624, 39.680	15.624, 39.680
	5%, 95%	5906.260, 24015.500	14817.300, 68488.300	5906.260, 68488.300	22.320, 35.960	15.624, 39.680	15.624, 39.680
	BLQ Values Included	0	0	0	3	2	5

PM3003537756

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	24088.700, 20855.600	40025.200, 35643.800	32057.000, 27264.900	36.833, 34.881	61.921, 41.943	49.377, 38.249
	SD, SE	14945.9000, 8629.0000	24816.8000, 14328.0000	20295.1000, 8285.4600	14.4738, 8.3564	62.6422, 36.1665	42.9212, 17.5225
	MEDIAN	21919.200	26983.200	25716.000	35.960	38.370	37.165
	MIN, MAX	10346.100, 40000.700	24448.700, 68643.800	10346.100, 68643.800	22.816, 51.724	14.467, 132.925	14.467, 132.925
	5%, 95%	10346.100, 40000.700	24448.700, 68643.800	10346.100, 68643.800	22.816, 51.724	14.467, 132.925	14.467, 132.925

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537757

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 178 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	4764.940, 4175.230	7997.910, 7671.640	6381.420, 5659.580	8.119, 7.437	12.018, 8.236	10.458, 7.907
	SD, SE	2902.0800, 1675.5100	2951.4800, 1704.0400	3160.5300, 1290.2800	4.6054, 3.2565	11.9592, 6.9046	9.0208, 4.0342
	MEDIAN	4179.610	6548.750	6299.940	8.119	7.646	7.646
	MIN, MAX	2200.136, 7915.062	6051.125, 11393.850	2200.136, 11393.850	4.862, 11.375	2.860, 25.548	2.860, 25.548
	5%, 95%	2200.140, 7915.060	6051.130, 11393.900	2200.140, 11393.900	4.862, 11.375	2.860, 25.548	2.860, 25.548
	BLQ Values Included	0	0	0	1	2	3

PM3003537758

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 179 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	4644.880, 4225.060	8715.750, 7683.640	6680.320, 5697.710	8.148, 7.208	4.666, 4.121	6.755, 5.764
	SD, SE	2513.2700, 1451.0400	5529.5500, 3192.4900	4441.6900, 1813.3100	4.8814, 2.8183	3.0922, 2.1865	4.2360, 1.8944
	MEDIAN	3843.180	6424.070	5562.270	6.912	4.666	6.852
	MIN, MAX	2630.266, 7461.200	4700.475, 15022.708	2630.266, 15022.708	4.004, 13.529	2.479, 6.852	2.479, 13.529
	5%, 95%	2630.270, 7461.200	4700.480, 15022.700	2630.270, 15022.700	4.004, 13.529	2.479, 6.852	2.479, 13.529
	BLQ Values Included	0	0	0	2	2	4

PM3003537759

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 180 of 7)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	2	5
	MEAN, GEO MEAN	2875.490, 2289.050	6364.890, 4871.210	4969.130, 3601.180	5.374, 5.264	5.315, 4.785	5.350, 5.067
	SD, SE	2461.1600, 1740.3000	5888.9000, 3399.9600	4744.1200, 2121.6400	1.3689, 0.7903	3.2690, 2.3115	1.8999, 0.8496
	MEDIAN	2875.490	3083.320	3083.320	4.919	5.315	4.919
	MIN, MAX	1135.184, 4615.788	2847.894, 13163.447	1135.184, 13163.447	4.290, 6.912	3.003, 7.626	3.003, 7.626
	5%, 95%	1135.180, 4615.790	2847.890, 13163.400	1135.180, 13163.400	4.290, 6.912	3.003, 7.626	3.003, 7.626
	BLQ Values Included	0	0	0	3	2	5

PM3003537760

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 181 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	4629.840, 4008.450	7692.840, 6850.720	6161.340, 5240.300	7.079, 6.704	11.901, 8.062	9.490, 7.352
	SD, SE	2872.5900, 1658.4900	4769.7600, 2753.8200	3900.7100, 1592.4600	2.7818, 1.6061	12.0395, 6.9510	8.2493, 3.3678
	MEDIAN	4212.860	5186.170	4942.610	6.912	7.375	7.144
	MIN, MAX	1988.530, 7688.130	4699.040, 13193.300	1988.530, 13193.300	4.385, 9.941	2.781, 25.548	2.781, 25.548
	5%, 95%	1988.530, 7688.130	4699.040, 13193.300	1988.530, 13193.300	4.385, 9.941	2.781, 25.548	2.781, 25.548

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537761

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	31.800, 31.800	NA, NA	31.800, 31.800
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	31.800	NA	31.800
	MIN, MAX	NA, NA	NA, NA	NA, NA	31.800, 31.800	NA, NA	31.800, 31.800
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	21069.900, 18521.300	33503.700, 32205.900	27286.800, 24423.200	20.929, 16.271	31.839, 22.520	27.163, 19.592
	SD, SE	12742.3000, 7356.7600	12057.0000, 6961.1100	13018.2000, 5314.6700	18.6740, 10.7815	24.8055, 12.4027	21.3986, 8.0879
	MEDIAN	18354.800	27146.300	26551.000	11.628	32.462	15.719
	MIN, MAX	9903.928, 34950.846	25955.790, 47408.910	9903.928, 47408.910	8.732, 42.427	5.880, 56.550	5.880, 56.550
	5%, 95%	9903.930, 34950.800	25955.800, 47408.900	9903.930, 47408.900	8.732, 42.427	5.880, 56.550	5.880, 56.550
	BLQ Values Included	0	0	0	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	47.850, 47.850	NA, NA	47.850, 47.850
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	47.850	NA	47.850
	MIN, MAX	NA, NA	NA, NA	NA, NA	47.850, 47.850	NA, NA	47.850, 47.850
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	2	4	6
	MEAN, GEO MEAN	18485.500, 16208.500	39076.000, 34277.600	28780.800, 23570.900	28.644, 22.502	20.636, 19.147	23.305, 20.206
	SD, SE	11611.4000, 6703.8700	25209.9000, 14554.9000	20864.7000, 8517.9700	25.0655, 17.7240	8.8182, 4.4091	13.7628, 5.6186
	MEDIAN	14936.900	28809.600	24714.300	28.644	20.185	20.185
	MIN, MAX	9062.489, 31457.230	20619.126, 67799.170	9062.489, 67799.170	10.920, 46.368	10.712, 31.460	10.712, 46.368
	5%, 95%	9062.490, 31457.200	20619.100, 67799.200	9062.490, 67799.200	10.920, 46.368	10.712, 31.460	10.712, 46.368
	BLQ Values Included	0	0	0	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 184 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	36.375, 36.375	NA, NA	36.375, 36.375
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	36.375	NA	36.375
	MIN, MAX	NA, NA	NA, NA	NA, NA	36.375, 36.375	NA, NA	36.375, 36.375
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	2	3	5	1	3	4
	MEAN, GEO MEAN	12276.900, 10259.200	26289.300, 21251.100	20684.400, 15880.900	14.448, 14.448	19.817, 17.623	18.475, 16.769
	SD, SE	9536.4300, 6743.2700	21906.0000, 12647.4000	17932.5000, 8019.6800	NA, NA	11.2455, 6.4926	9.5662, 4.7831
	MEDIAN	12276.900	13910.500	13910.500	14.448	18.228	16.338
	MIN, MAX	5533.662, 19020.205	13375.150, 51582.300	5533.662, 51582.300	14.448, 14.448	9.450, 31.772	9.450, 31.772
	5%, 95%	5533.660, 19020.200	13375.200, 51582.300	5533.660, 51582.300	NA, NA	9.450, 31.772	9.450, 31.772
	BLQ Values Included	0	0	0	0	0	0

PM3003537764

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	38.675, 38.675	NA, NA	38.675, 38.675
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	38.675	NA	38.675
	MIN, MAX	NA, NA	NA, NA	NA, NA	38.675, 38.675	NA, NA	38.675, 38.675
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	19602.700, 16784.400	32956.300, 29610.300	26279.500, 22293.300	18.140, 15.019	23.819, 20.460	21.385, 17.921
	SD, SE	12658.3000, 7308.2900	19636.8000, 11337.3000	16487.3000, 6730.9100	14.1509, 8.1700	13.4686, 6.7343	12.9100, 4.8795
	MEDIAN	17437.300	22713.500	21636.100	11.274	24.725	16.485
	MIN, MAX	8166.690, 33204.000	20558.600, 55596.800	8166.690, 55596.800	8.732, 34.414	8.681, 37.147	8.681, 37.147
	5%, 95%	8166.690, 33204.000	20558.600, 55596.800	8166.690, 55596.800	8.732, 34.414	8.681, 37.147	8.681, 37.147

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537765

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 186 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	6.112, 6.112	NA, NA	6.112, 6.112
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	6.112	NA	6.112
	MIN, MAX	NA, NA	NA, NA	NA, NA	6.112, 6.112	NA, NA	6.112, 6.112
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	4049.630, 3559.800	6439.400, 6189.970	5244.520, 4694.150	4.022, 3.127	6.119, 4.328	5.221, 3.765
	SD, SE	2449.0700, 1413.9700	2317.3600, 1337.9300	2502.1100, 1021.4800	3.5890, 2.0721	4.7677, 2.3838	4.1128, 1.5545
	MEDIAN	3527.800	5217.520	5103.110	2.235	6.239	3.021
	MIN, MAX	1903.535, 6717.553	4988.703, 9111.993	1903.535, 9111.993	1.678, 8.154	1.130, 10.869	1.130, 10.869
	5%, 95%	1903.540, 6717.550	4988.700, 9111.990	1903.540, 9111.990	1.678, 8.154	1.130, 10.869	1.130, 10.869
	BLQ Values Included	0	0	0	0	0	0

PM3003537766

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	9.197, 9.197	NA, NA	9.197, 9.197
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	9.197	NA	9.197
	MIN, MAX	NA, NA	NA, NA	NA, NA	9.197, 9.197	NA, NA	9.197, 9.197
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	2	4	6
	MEAN, GEO MEAN	3552.920, 3115.270	7510.400, 6588.160	5531.660, 4530.330	5.506, 4.325	3.966, 3.680	4.479, 3.884
	SD, SE	2231.7200, 1288.4800	4845.3400, 2797.4600	4010.1900, 1637.1500	4.8175, 3.4065	1.6950, 0.8475	2.6453, 1.0799
	MEDIAN	2870.880	5537.200	4750.100	5.506	3.880	3.880
	MIN, MAX	1741.810, 6046.080	3962.996, 13031.000	1741.810, 13031.000	2.099, 8.912	2.059, 6.047	2.059, 8.912
	5%, 95%	1741.810, 6046.080	3963.000, 13031.000	1741.810, 13031.000	2.099, 8.912	2.059, 6.047	2.059, 8.912
	BLQ Values Included	0	0	0	0	0	0

PM3003537767

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	6.991, 6.991	NA, NA	6.991, 6.991
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	6.991	NA	6.991
	MIN, MAX	NA, NA	NA, NA	NA, NA	6.991, 6.991	NA, NA	6.991, 6.991
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	2	3	5	1	3	4
	MEAN, GEO MEAN	2359.630, 1971.820	5052.810, 4084.460	3975.540, 3052.300	2.777, 2.777	3.809, 3.387	3.551, 3.223
	SD, SE	1832.9000, 1296.0600	4210.3300, 2430.8400	3446.6400, 1541.3800	NA, NA	2.1618, 1.2481	1.8389, 0.9195
	MEDIAN	2359.630	2673.600	2673.600	2.777	3.503	3.140
	MIN, MAX	1063.570, 3655.683	2570.704, 9914.118	1063.570, 9914.118	2.777, 2.777	1.816, 6.107	1.816, 6.107
	5%, 95%	1063.570, 3655.680	2570.700, 9914.120	1063.570, 9914.120	NA, NA	1.816, 6.107	1.816, 6.107
	BLQ Values Included	0	0	0	0	0	0

PM3003537768

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	7.433, 7.433	NA, NA	7.433, 7.433
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	7.433	NA	7.433
	MIN, MAX	NA, NA	NA, NA	NA, NA	7.433, 7.433	NA, NA	7.433, 7.433
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3767.640, 3225.960	6334.200, 5691.100	5050.920, 4284.770	3.486, 2.887	4.578, 3.932	4.110, 3.444
	SD, SE	2432.9400, 1404.6600	3774.1900, 2179.0300	3168.8600, 1293.6800	2.7197, 1.5702	2.5891, 1.2946	2.4815, 0.9379
	MEDIAN	3351.450	4365.540	4158.460	2.167	4.752	3.168
	MIN, MAX	1569.640, 6381.820	3951.370, 10685.700	1569.640, 10685.700	1.678, 6.614	1.668, 7.140	1.668, 7.140
	5%, 95%	1569.640, 6381.820	3951.370, 10685.700	1569.640, 10685.700	1.678, 6.614	1.668, 7.140	1.668, 7.140

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537769

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.015, 0.015	NA, NA	0.015, 0.015
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.015	NA	0.015
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.015, 0.015	NA, NA	0.015, 0.015
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	11.833, 10.243	6.930, 6.137	9.381, 7.928	NA, NA	0.029, 0.027	0.029, 0.027
	SD, SE	6.6791, 3.8562	3.5278, 2.0368	5.4803, 2.2373	NA, NA	0.0141, 0.0100	0.0141, 0.0100
	MEDIAN	13.088	8.454	8.947	NA	0.029	0.029
	MIN, MAX	4.615, 17.795	2.896, 9.439	2.896, 17.795	NA, NA	0.019, 0.039	0.019, 0.039
	5%, 95%	4.615, 17.795	2.896, 9.439	2.896, 17.795	NA, NA	0.019, 0.039	0.019, 0.039
	BLQ Values Included	0	0	0	NA	2	2

PM3003537770

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 191 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.016	NA	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	3	4
	MEAN, GEO MEAN	11.371, 10.429	8.138, 7.501	9.755, 8.845	0.026, 0.026	0.038, 0.037	0.035, 0.034
	SD, SE	5.8605, 3.3836	3.5658, 2.0587	4.6862, 1.9131	NA, NA	0.0093, 0.0054	0.0096, 0.0048
	MEDIAN	9.627	9.321	9.474	0.026	0.042	0.035
	MIN, MAX	6.581, 17.906	4.131, 10.962	4.131, 17.906	0.026, 0.026	0.027, 0.044	0.026, 0.044
	5%, 95%	6.581, 17.906	4.131, 10.962	4.131, 17.906	NA, NA	0.027, 0.044	0.026, 0.044
	BLQ Values Included	0	0	0	1	2	3

PM3003537771

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 192 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.016	NA	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	8.146, 7.454	8.716, 8.167	8.488, 7.874	0.022, 0.021	0.022, 0.021	0.022, 0.021
	SD, SE	4.6457, 3.2850	4.0438, 2.3347	3.6972, 1.6534	0.0062, 0.0036	0.0082, 0.0047	0.0065, 0.0027
	MEDIAN	8.146	6.628	6.628	0.024	0.024	0.024
	MIN, MAX	4.861, 11.431	6.143, 13.377	4.861, 13.377	0.015, 0.027	0.013, 0.029	0.013, 0.029
	5%, 95%	4.861, 11.431	6.143, 13.377	4.861, 13.377	0.015, 0.027	0.013, 0.029	0.013, 0.029
	BLQ Values Included	0	0	0	3	3	6

PM3003537772

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 193 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.016	NA	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	10.807, 9.848	7.928, 7.381	9.367, 8.525	0.022, 0.022	0.030, 0.030	0.026, 0.026
	SD, SE	5.2014, 3.0030	3.4391, 1.9856	4.2474, 1.7340	0.0064, 0.0037	0.0047, 0.0027	0.0067, 0.0027
	MEDIAN	11.358	8.134	9.697	0.025	0.032	0.026
	MIN, MAX	5.352, 15.711	4.390, 11.259	4.390, 15.711	0.015, 0.027	0.025, 0.034	0.015, 0.034
	5%, 95%	5.352, 15.711	4.390, 11.259	4.390, 15.711	0.015, 0.027	0.025, 0.034	0.015, 0.034

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 194 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.002	NA	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	1.919, 1.662	1.124, 0.995	1.522, 1.286	NA, NA	0.005, 0.004	0.005, 0.004
	SD, SE	1.0830, 0.6252	0.5720, 0.3302	0.8887, 0.3628	NA, NA	0.0021, 0.0015	0.0021, 0.0015
	MEDIAN	2.123	1.371	1.451	NA	0.005	0.005
	MIN, MAX	0.749, 2.886	0.470, 1.531	0.470, 2.886	NA, NA	0.003, 0.006	0.003, 0.006
	5%, 95%	0.749, 2.886	0.470, 1.531	0.470, 2.886	NA, NA	0.003, 0.006	0.003, 0.006
	BLQ Values Included	0	0	0	NA	2	2

PM3003537774

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 195 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.003	NA	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	3	4
	MEAN, GEO MEAN	1.844, 1.691	1.320, 1.217	1.582, 1.434	0.004, 0.004	0.006, 0.006	0.006, 0.005
	SD, SE	0.9506, 0.5489	0.5784, 0.3339	0.7601, 0.3103	NA, NA	0.0017, 0.0010	0.0017, 0.0009
	MEDIAN	1.561	1.512	1.537	0.004	0.007	0.006
	MIN, MAX	1.067, 2.904	0.670, 1.778	0.670, 2.904	0.004, 0.004	0.004, 0.007	0.004, 0.007
	5%, 95%	1.067, 2.904	0.670, 1.778	0.670, 2.904	NA, NA	0.004, 0.007	0.004, 0.007
	BLQ Values Included	0	0	0	1	2	3

PM3003537775

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 196 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.003	NA	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	1.321, 1.209	1.414, 1.324	1.377, 1.277	0.003, 0.003	0.004, 0.003	0.004, 0.003
	SD, SE	0.7538, 0.5330	0.6562, 0.3789	0.5999, 0.2683	0.0012, 0.0007	0.0015, 0.0009	0.0012, 0.0005
	MEDIAN	1.321	1.075	1.075	0.004	0.004	0.004
	MIN, MAX	0.788, 1.854	0.996, 2.170	0.788, 2.170	0.002, 0.004	0.002, 0.005	0.002, 0.005
	5%, 95%	0.788, 1.854	0.996, 2.170	0.788, 2.170	0.002, 0.004	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	3	3	6

PM3003537776

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.003	NA	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	1.753, 1.597	1.286, 1.197	1.519, 1.383	0.003, 0.003	0.005, 0.005	0.004, 0.004
	SD, SE	0.8436, 0.4870	0.5577, 0.3220	0.6888, 0.2812	0.0012, 0.0007	0.0010, 0.0006	0.0013, 0.0005
	MEDIAN	1.842	1.319	1.573	0.004	0.005	0.004
	MIN, MAX	0.868, 2.548	0.712, 1.826	0.712, 2.548	0.002, 0.004	0.004, 0.006	0.002, 0.006
	5%, 95%	0.868, 2.548	0.712, 1.826	0.712, 2.548	0.002, 0.004	0.004, 0.006	0.002, 0.006

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537777

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.004	NA	0.004
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	9.355, 8.398	3.908, 3.497	6.631, 5.419	0.005, 0.005	0.005, 0.005	0.005, 0.005
	SD, SE	4.5544, 2.6295	1.9305, 1.1146	4.3231, 1.7649	NA, NA	NA, NA	0.0000, 0.0000
	MEDIAN	11.224	4.646	5.003	0.005	0.005	0.005
	MIN, MAX	4.163, 12.677	1.717, 5.360	1.717, 12.677	0.005, 0.005	0.005, 0.005	0.005, 0.005
	5%, 95%	4.163, 12.677	1.717, 5.360	1.717, 12.677	NA, NA	NA, NA	0.005, 0.005
	BLQ Values Included	0	0	0	1	1	2

PM3003537778

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 199 of 7)

Lab: INBIFO
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	7.655, 6.831	5.173, 4.551	6.414, 5.576	NA, NA	0.008, 0.006	0.008, 0.006
	SD, SE	4.2280, 2.4410	2.7852, 1.6080	3.4787, 1.4202	NA, NA	0.0064, 0.0045	0.0064, 0.0045
	MEDIAN	7.258	5.707	6.483	NA	0.008	0.008
	MIN, MAX	3.639, 12.067	2.159, 7.652	2.159, 12.067	NA, NA	0.003, 0.012	0.003, 0.012
	5%, 95%	3.639, 12.067	2.159, 7.652	2.159, 12.067	NA, NA	0.003, 0.012	0.003, 0.012
	BLQ Values Included	0	0	0	NA	2	2

PM3003537779

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 200 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	5.211, 5.015	5.608, 5.258	5.449, 5.159	0.006, 0.005	0.006, 0.005	0.006, 0.005
	SD, SE	2.0011, 1.4150	2.5268, 1.4588	2.0593, 0.9210	0.0021, 0.0015	0.0035, 0.0025	0.0024, 0.0012
	MEDIAN	5.211	4.773	4.773	0.006	0.006	0.006
	MIN, MAX	3.796, 6.626	3.605, 8.447	3.605, 8.447	0.004, 0.007	0.003, 0.008	0.003, 0.008
	5%, 95%	3.796, 6.626	3.605, 8.447	3.605, 8.447	0.004, 0.007	0.003, 0.008	0.003, 0.008
	BLQ Values Included	0	0	0	2	2	4

PM3003537780

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 201 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.004	NA	0.004
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	7.855, 7.202	4.896, 4.578	6.376, 5.742	0.005, 0.005	0.008, 0.007	0.007, 0.006
	SD, SE	3.5074, 2.0250	2.1454, 1.2386	3.0639, 1.2508	0.0014, 0.0010	0.0040, 0.0023	0.0033, 0.0015
	MEDIAN	9.241	4.653	5.903	0.005	0.008	0.006
	MIN, MAX	3.866, 10.457	2.883, 7.153	2.883, 10.457	0.004, 0.006	0.004, 0.012	0.004, 0.012
	5%, 95%	3.866, 10.457	2.883, 7.153	2.883, 10.457	0.004, 0.006	0.004, 0.012	0.004, 0.012

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537781

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.001	NA	0.001
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	1.517, 1.362	0.634, 0.567	1.076, 0.879	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.7389, 0.4266	0.3133, 0.1809	0.7014, 0.2863	NA, NA	NA, NA	0.0000, 0.0000
	MEDIAN	1.821	0.754	0.812	0.001	0.001	0.001
	MIN, MAX	0.675, 2.056	0.278, 0.869	0.278, 2.056	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	0.675, 2.056	0.278, 0.869	0.278, 2.056	NA, NA	NA, NA	0.001, 0.001
	BLQ Values Included	0	0	0	1	1	2

PM3003537782

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 203 of 7)

Lab: INBIFO
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	1.241, 1.108	0.839, 0.738	1.040, 0.904	NA, NA	0.001, NA	0.001, NA
	SD, SE	0.6858, 0.3959	0.4518, 0.2609	0.5642, 0.2303	NA, NA	0.0014, 0.0010	0.0014, 0.0010
	MEDIAN	1.177	0.926	1.052	NA	0.001	0.001
	MIN, MAX	0.590, 1.957	0.350, 1.241	0.350, 1.957	NA, NA	0.000, 0.002	0.000, 0.002
	5%, 95%	0.590, 1.957	0.350, 1.241	0.350, 1.957	NA, NA	0.000, 0.002	0.000, 0.002
	BLQ Values Included	0	0	0	NA	2	2

PM3003537783

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 204 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	0.846, 0.814	0.910, 0.853	0.884, 0.837	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	0.3246, 0.2295	0.4097, 0.2365	0.3339, 0.1493	0.0000, 0.0000	0.0007, 0.0005	0.0005, 0.0003
	MEDIAN	0.846	0.774	0.774	0.001	0.001	0.001
	MIN, MAX	0.616, 1.075	0.585, 1.370	0.585, 1.370	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	0.616, 1.075	0.585, 1.370	0.585, 1.370	0.001, 0.001	0.000, 0.001	0.000, 0.001
	BLQ Values Included	0	0	0	2	2	4

PM3003537784

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.001	NA	0.001
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	1.274, 1.168	0.794, 0.742	1.034, 0.931	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	0.5689, 0.3285	0.3481, 0.2010	0.4971, 0.2029	0.0000, 0.0000	0.0010, 0.0006	0.0007, 0.0003
	MEDIAN	1.499	0.755	0.958	0.001	0.001	0.001
	MIN, MAX	0.627, 1.696	0.467, 1.160	0.467, 1.696	0.001, 0.001	0.000, 0.002	0.000, 0.002
	5%, 95%	0.627, 1.696	0.467, 1.160	0.467, 1.696	0.001, 0.001	0.000, 0.002	0.000, 0.002

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537785

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.013, 0.013	NA, NA	0.013, 0.013
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.013	NA	0.013
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.013, 0.013	NA, NA	0.013, 0.013
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	13.511, 10.048	18.355, 16.426	15.933, 12.847	0.011, 0.010	0.026, 0.024	0.017, 0.014
	SD, SE	10.5711, 6.1032	8.9922, 5.1917	9.1696, 3.7435	0.0057, 0.0033	0.0120, 0.0085	0.0109, 0.0049
	MEDIAN	12.992	22.634	17.813	0.009	0.026	0.017
	MIN, MAX	3.209, 24.332	8.022, 24.408	3.209, 24.408	0.006, 0.017	0.017, 0.034	0.006, 0.034
	5%, 95%	3.209, 24.332	8.022, 24.408	3.209, 24.408	0.006, 0.017	0.017, 0.034	0.006, 0.034
	BLQ Values Included	0	0	0	3	2	5

PM3003537786

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.014, 0.014	NA, NA	0.014, 0.014
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.014	NA	0.014
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.014, 0.014	NA, NA	0.014, 0.014
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	16.083, 14.140	18.664, 17.252	17.374, 15.619	0.014, 0.013	0.023, 0.020	0.019, 0.016
	SD, SE	9.3691, 5.4093	8.6313, 4.9833	8.1799, 3.3394	0.0081, 0.0047	0.0145, 0.0084	0.0116, 0.0047
	MEDIAN	15.174	18.349	16.762	0.013	0.023	0.018
	MIN, MAX	7.201, 25.873	10.195, 27.449	7.201, 27.449	0.007, 0.023	0.009, 0.038	0.007, 0.038
	5%, 95%	7.201, 25.873	10.195, 27.449	7.201, 27.449	0.007, 0.023	0.009, 0.038	0.007, 0.038
	BLQ Values Included	0	0	0	3	3	6

PM3003537787

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 208 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.014, 0.014	NA, NA	0.014, 0.014
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.014	NA	0.014
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.014, 0.014	NA, NA	0.014, 0.014
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	14.863, 10.507	17.379, 15.650	16.373, 13.344	0.019, 0.018	0.018, 0.017	0.019, 0.018
	SD, SE	14.8662, 10.5120	8.5251, 4.9219	9.6689, 4.3241	0.0053, 0.0031	0.0064, 0.0037	0.0053, 0.0022
	MEDIAN	14.863	19.648	19.648	0.021	0.021	0.021
	MIN, MAX	4.351, 25.375	7.949, 24.540	4.351, 25.375	0.013, 0.023	0.011, 0.023	0.011, 0.023
	5%, 95%	4.351, 25.375	7.949, 24.540	4.351, 25.375	0.013, 0.023	0.011, 0.023	0.011, 0.023
	BLQ Values Included	0	0	0	3	3	6

PM3003537788

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.014, 0.014	NA, NA	0.014, 0.014
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.014	NA	0.014
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.014, 0.014	NA, NA	0.014, 0.014
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	14.732, 12.041	18.133, 16.559	16.432, 14.120	0.015, 0.014	0.024, 0.022	0.020, 0.018
	SD, SE	10.1521, 5.8613	8.2106, 4.7404	8.4653, 3.4559	0.0052, 0.0030	0.0083, 0.0041	0.0080, 0.0030
	MEDIAN	14.083	21.841	17.962	0.018	0.026	0.018
	MIN, MAX	4.920, 25.193	8.722, 23.835	4.920, 25.193	0.009, 0.018	0.012, 0.030	0.009, 0.030
	5%, 95%	4.920, 25.193	8.722, 23.835	4.920, 25.193	0.009, 0.018	0.012, 0.030	0.009, 0.030

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537789

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 210 of 7)

Lab: INBIFO
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.002	NA	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	2.380, 1.770	3.234, 2.894	2.807, 2.263	0.002, 0.002	0.005, 0.004	0.003, 0.003
	SD, SE	1.8627, 1.0754	1.5848, 0.9150	1.6139, 0.6597	0.0010, 0.0006	0.0021, 0.0015	0.0019, 0.0008
	MEDIAN	2.289	3.988	3.139	0.002	0.005	0.003
	MIN, MAX	0.565, 4.287	1.413, 4.301	0.565, 4.301	0.001, 0.003	0.003, 0.006	0.001, 0.006
	5%, 95%	0.565, 4.287	1.413, 4.301	0.565, 4.301	0.001, 0.003	0.003, 0.006	0.001, 0.006
	BLQ Values Included	0	0	0	3	2	5

PM3003537790

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.002	NA	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	2.834, 2.492	3.289, 3.040	3.061, 2.752	0.002, 0.002	0.004, 0.004	0.003, 0.003
	SD, SE	1.6508, 0.9531	1.5213, 0.8783	1.4415, 0.5885	0.0015, 0.0009	0.0025, 0.0015	0.0022, 0.0009
	MEDIAN	2.674	3.233	2.954	0.002	0.004	0.003
	MIN, MAX	1.269, 4.559	1.796, 4.837	1.269, 4.837	0.001, 0.004	0.002, 0.007	0.001, 0.007
	5%, 95%	1.269, 4.559	1.796, 4.837	1.269, 4.837	0.001, 0.004	0.002, 0.007	0.001, 0.007
	BLQ Values Included	0	0	0	3	3	6

PM3003537791

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 212 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.002	NA	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	2.619, 1.852	3.062, 2.758	2.885, 2.352	0.003, 0.003	0.003, 0.003	0.003, 0.003
	SD, SE	2.6191, 1.8520	1.5019, 0.8671	1.7035, 0.7618	0.0012, 0.0007	0.0012, 0.0007	0.0010, 0.0004
	MEDIAN	2.619	3.462	3.462	0.004	0.004	0.004
	MIN, MAX	0.767, 4.471	1.401, 4.324	0.767, 4.471	0.002, 0.004	0.002, 0.004	0.002, 0.004
	5%, 95%	0.767, 4.471	1.401, 4.324	0.767, 4.471	0.002, 0.004	0.002, 0.004	0.002, 0.004
	BLQ Values Included	0	0	0	3	3	6

PM3003537792

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.002	NA	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	2.596, 2.122	3.195, 2.918	2.896, 2.488	0.002, 0.002	0.004, 0.004	0.003, 0.003
	SD, SE	1.7887, 1.0327	1.4466, 0.8352	1.4915, 0.6089	0.0012, 0.0007	0.0017, 0.0009	0.0017, 0.0006
	MEDIAN	2.482	3.848	3.165	0.003	0.005	0.003
	MIN, MAX	0.867, 4.439	1.537, 4.200	0.867, 4.439	0.001, 0.003	0.002, 0.006	0.001, 0.006
	5%, 95%	0.867, 4.439	1.537, 4.200	0.867, 4.439	0.001, 0.003	0.002, 0.006	0.001, 0.006

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537793

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 214 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.004	NA	0.004
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	4.952, 4.530	7.459, 6.305	6.206, 5.345	0.007, 0.006	0.007, 0.006	0.007, 0.006
	SD, SE	2.3935, 1.3819	4.4571, 2.5733	3.4820, 1.4215	0.0047, 0.0027	0.0029, 0.0017	0.0035, 0.0014
	MEDIAN	4.962	8.305	6.151	0.005	0.005	0.005
	MIN, MAX	2.553, 7.340	2.640, 11.433	2.553, 11.433	0.003, 0.012	0.005, 0.010	0.003, 0.012
	5%, 95%	2.553, 7.340	2.640, 11.433	2.553, 11.433	0.003, 0.012	0.005, 0.010	0.003, 0.012
	BLQ Values Included	0	0	0	2	3	5

PM3003537794

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.004	NA	0.004
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	5.895, 5.703	8.269, 7.266	7.082, 6.437	0.004, 0.004	0.007, 0.006	0.005, 0.005
	SD, SE	1.9382, 1.1190	5.2339, 3.0218	3.7617, 1.5357	0.0020, 0.0012	0.0034, 0.0017	0.0030, 0.0011
	MEDIAN	4.778	6.393	5.586	0.004	0.006	0.005
	MIN, MAX	4.774, 8.133	4.231, 14.182	4.231, 14.182	0.002, 0.006	0.003, 0.011	0.002, 0.011
	5%, 95%	4.774, 8.133	4.231, 14.182	4.231, 14.182	0.002, 0.006	0.003, 0.011	0.002, 0.011
	BLQ Values Included	0	0	0	3	4	7

PM3003537795

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 216 of 7)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	4	7
	MEAN, GEO MEAN	6.742, 6.040	6.759, 6.029	6.752, 6.033	0.005, 0.005	0.006, 0.005	0.005, 0.005
	SD, SE	4.2370, 2.9960	3.5104, 2.0267	3.2634, 1.4594	0.0012, 0.0007	0.0017, 0.0009	0.0014, 0.0005
	MEDIAN	6.742	7.282	7.282	0.006	0.006	0.006
	MIN, MAX	3.746, 9.738	3.016, 9.978	3.016, 9.978	0.004, 0.006	0.003, 0.007	0.003, 0.007
	5%, 95%	3.746, 9.738	3.016, 9.978	3.016, 9.978	0.004, 0.006	0.003, 0.007	0.003, 0.007
	BLQ Values Included	0	0	0	3	4	7

PM3003537796

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Cotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.004	NA	0.004
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	5.655, 5.326	7.496, 6.674	6.575, 5.962	0.005, 0.005	0.007, 0.006	0.006, 0.006
	SD, SE	2.4525, 1.4160	3.8867, 2.2440	3.0766, 1.2560	0.0006, 0.0003	0.0024, 0.0012	0.0018, 0.0007
	MEDIAN	4.868	8.225	6.547	0.005	0.007	0.005
	MIN, MAX	3.692, 8.404	3.296, 10.966	3.296, 10.966	0.005, 0.006	0.004, 0.009	0.004, 0.009
	5%, 95%	3.692, 8.404	3.296, 10.966	3.296, 10.966	0.005, 0.006	0.004, 0.009	0.004, 0.009

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537797

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 218 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.001	NA	0.001
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	0.872, 0.798	1.314, 1.111	1.093, 0.942	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.4215, 0.2434	0.7852, 0.4533	0.6133, 0.2504	0.0006, 0.0003	0.0006, 0.0003	0.0005, 0.0002
	MEDIAN	0.874	1.463	1.084	0.001	0.001	0.001
	MIN, MAX	0.450, 1.293	0.465, 2.014	0.450, 2.014	0.001, 0.002	0.001, 0.002	0.001, 0.002
	5%, 95%	0.450, 1.293	0.465, 2.014	0.450, 2.014	0.001, 0.002	0.001, 0.002	0.001, 0.002
	BLQ Values Included	0	0	0	2	3	5

PM3003537798

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 219 of 7)

Lab: INBIFO
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.001	NA	0.001
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	1.039, 1.005	1.457, 1.280	1.248, 1.134	0.001, NA	0.001, 0.001	0.001, NA
	SD, SE	0.3415, 0.1972	0.9222, 0.5324	0.6628, 0.2706	0.0006, 0.0003	0.0005, 0.0003	0.0006, 0.0002
	MEDIAN	0.842	1.126	0.984	0.001	0.001	0.001
	MIN, MAX	0.841, 1.433	0.746, 2.499	0.746, 2.499	0.000, 0.001	0.001, 0.002	0.000, 0.002
	5%, 95%	0.841, 1.433	0.746, 2.499	0.746, 2.499	0.000, 0.001	0.001, 0.002	0.000, 0.002
	BLQ Values Included	0	0	0	3	4	7

PM3003537799

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 220 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	4	7
	MEAN, GEO MEAN	1.188, 1.064	1.191, 1.062	1.190, 1.063	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.7467, 0.5280	0.6187, 0.3572	0.5751, 0.2572	0.0000, 0.0000	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	1.188	1.283	1.283	0.001	0.001	0.001
	MIN, MAX	0.660, 1.716	0.531, 1.758	0.531, 1.758	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	0.660, 1.716	0.531, 1.758	0.531, 1.758	0.001, 0.001	0.001, 0.001	0.001, 0.001
	BLQ Values Included	0	0	0	3	4	7

PM3003537800

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Cotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.001	NA	0.001
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	0.997, 0.939	1.321, 1.176	1.159, 1.051	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.4320, 0.2494	0.6846, 0.3952	0.5419, 0.2212	0.0000, 0.0000	0.0005, 0.0003	0.0004, 0.0001
	MEDIAN	0.858	1.449	1.154	0.001	0.001	0.001
	MIN, MAX	0.651, 1.481	0.581, 1.932	0.581, 1.932	0.001, 0.001	0.001, 0.002	0.001, 0.002
	5%, 95%	0.651, 1.481	0.581, 1.932	0.581, 1.932	0.001, 0.001	0.001, 0.002	0.001, 0.002

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537801

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	15.979, 14.956	36.794, 30.430	26.386, 21.334	0.022, 0.022	0.051, 0.041	0.040, 0.032
	SD, SE	6.9296, 4.0008	28.8498, 16.6564	21.9570, 8.9639	0.0042, 0.0030	0.0400, 0.0231	0.0326, 0.0146
	MEDIAN	15.278	22.427	20.188	0.022	0.039	0.025
	MIN, MAX	9.426, 23.232	17.948, 70.006	9.426, 70.006	0.019, 0.025	0.019, 0.096	0.019, 0.096
	5%, 95%	9.426, 23.232	17.948, 70.006	9.426, 70.006	0.019, 0.025	0.019, 0.096	0.019, 0.096
	BLQ Values Included	0	0	0	1	2	3

PM3003537802

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 223 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	19.232, 18.698	38.488, 29.184	28.860, 23.360	0.022, 0.022	0.019, 0.017	0.021, 0.020
	SD, SE	5.6416, 3.2572	35.6930, 20.6074	25.1708, 10.2759	0.0064, 0.0037	0.0106, 0.0075	0.0073, 0.0032
	MEDIAN	18.022	21.151	19.587	0.026	0.019	0.026
	MIN, MAX	14.293, 25.380	14.775, 79.538	14.293, 79.538	0.015, 0.026	0.011, 0.026	0.011, 0.026
	5%, 95%	14.293, 25.380	14.775, 79.538	14.293, 79.538	0.015, 0.026	0.011, 0.026	0.011, 0.026
	BLQ Values Included	0	0	0	2	2	4

PM3003537803

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	2	5
	MEAN, GEO MEAN	14.967, 14.298	30.402, 21.584	24.228, 18.306	0.021, 0.021	0.020, 0.018	0.021, 0.020
	SD, SE	6.2579, 4.4250	30.8849, 17.8314	23.6263, 10.5660	0.0057, 0.0033	0.0113, 0.0080	0.0070, 0.0031
	MEDIAN	14.967	15.321	15.321	0.023	0.020	0.023
	MIN, MAX	10.542, 19.392	9.955, 65.930	9.955, 65.930	0.015, 0.026	0.012, 0.028	0.012, 0.028
	5%, 95%	10.542, 19.392	9.955, 65.930	9.955, 65.930	0.015, 0.026	0.012, 0.028	0.012, 0.028
	BLQ Values Included	0	0	0	3	2	5

PM3003537804

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 225 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	17.763, 16.956	35.228, 27.172	26.496, 21.465	0.022, 0.022	0.047, 0.035	0.035, 0.028
	SD, SE	6.4453, 3.7212	31.8090, 18.3650	22.6461, 9.2452	0.0025, 0.0015	0.0433, 0.0250	0.0306, 0.0125
	MEDIAN	17.564	19.633	18.599	0.022	0.031	0.024
	MIN, MAX	11.420, 24.306	14.226, 71.825	11.420, 71.825	0.020, 0.025	0.014, 0.096	0.014, 0.096
	5%, 95%	11.420, 24.306	14.226, 71.825	11.420, 71.825	0.020, 0.025	0.014, 0.096	0.014, 0.096

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537805

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	3.071, 2.875	7.072, 5.849	5.071, 4.100	0.005, 0.004	0.010, 0.008	0.008, 0.006
	SD, SE	1.3316, 0.7688	5.5448, 3.2013	4.2201, 1.7228	0.0007, 0.0005	0.0074, 0.0043	0.0059, 0.0027
	MEDIAN	2.936	4.310	3.880	0.005	0.007	0.005
	MIN, MAX	1.812, 4.465	3.450, 13.455	1.812, 13.455	0.004, 0.005	0.004, 0.018	0.004, 0.018
	5%, 95%	1.812, 4.465	3.450, 13.455	1.812, 13.455	0.004, 0.005	0.004, 0.018	0.004, 0.018
	BLQ Values Included	0	0	0	1	2	3

PM3003537806

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	3.696, 3.594	7.397, 5.609	5.547, 4.490	0.004, 0.004	0.004, 0.003	0.004, 0.004
	SD, SE	1.0843, 0.6260	6.8601, 3.9607	4.8377, 1.9750	0.0012, 0.0007	0.0021, 0.0015	0.0014, 0.0006
	MEDIAN	3.464	4.065	3.765	0.005	0.004	0.005
	MIN, MAX	2.747, 4.878	2.840, 15.287	2.747, 15.287	0.003, 0.005	0.002, 0.005	0.002, 0.005
	5%, 95%	2.747, 4.878	2.840, 15.287	2.747, 15.287	0.003, 0.005	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	2	2	4

PM3003537807

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	2	5
	MEAN, GEO MEAN	2.877, 2.748	5.843, 4.148	4.657, 3.518	0.004, 0.004	0.004, 0.003	0.004, 0.004
	SD, SE	1.2028, 0.8505	5.9363, 3.4273	4.5411, 2.0309	0.0010, 0.0006	0.0021, 0.0015	0.0013, 0.0006
	MEDIAN	2.877	2.945	2.945	0.004	0.004	0.004
	MIN, MAX	2.026, 3.727	1.913, 12.672	1.913, 12.672	0.003, 0.005	0.002, 0.005	0.002, 0.005
	5%, 95%	2.026, 3.727	1.913, 12.672	1.913, 12.672	0.003, 0.005	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	3	2	5

PM3003537808

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3.414, 3.259	6.771, 5.222	5.093, 4.126	0.004, 0.004	0.009, 0.007	0.007, 0.005
	SD, SE	1.2389, 0.7153	6.1140, 3.5299	4.3527, 1.7770	0.0006, 0.0003	0.0079, 0.0046	0.0056, 0.0023
	MEDIAN	3.376	3.773	3.575	0.004	0.006	0.005
	MIN, MAX	2.195, 4.672	2.734, 13.805	2.195, 13.805	0.004, 0.005	0.003, 0.018	0.003, 0.018
	5%, 95%	2.195, 4.672	2.734, 13.805	2.195, 13.805	0.004, 0.005	0.003, 0.018	0.003, 0.018

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537809

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.012, 0.012	NA, NA	0.012, 0.012
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.012	NA	0.012
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.012, 0.012	NA, NA	0.012, 0.012
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	13.589, 12.752	29.592, 24.553	21.591, 17.695	0.011, 0.009	0.024, 0.019	0.018, 0.014
	SD, SE	5.8121, 3.3556	22.9539, 13.2525	17.3519, 7.0839	0.0067, 0.0038	0.0157, 0.0079	0.0137, 0.0052
	MEDIAN	12.896	18.489	16.395	0.009	0.024	0.015
	MIN, MAX	8.155, 19.717	14.300, 55.986	8.155, 55.986	0.005, 0.018	0.007, 0.041	0.005, 0.041
	5%, 95%	8.155, 19.717	14.300, 55.986	8.155, 55.986	0.005, 0.018	0.007, 0.041	0.005, 0.041
	BLQ Values Included	0	0	0	0	0	0

PM3003537810

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.021, 0.021	NA, NA	0.021, 0.021
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.021	NA	0.021
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.021, 0.021	NA, NA	0.021, 0.021
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	2	4	6
	MEAN, GEO MEAN	14.498, 13.787	33.227, 25.023	23.863, 18.574	0.013, 0.012	0.017, 0.016	0.016, 0.014
	SD, SE	5.6224, 3.2461	31.1085, 17.9605	22.4716, 9.1740	0.0064, 0.0045	0.0074, 0.0037	0.0069, 0.0028
	MEDIAN	13.463	18.231	15.847	0.013	0.018	0.015
	MIN, MAX	9.465, 20.566	12.457, 68.993	9.465, 68.993	0.008, 0.017	0.009, 0.024	0.008, 0.024
	5%, 95%	9.465, 20.566	12.457, 68.993	9.465, 68.993	0.008, 0.017	0.009, 0.024	0.008, 0.024
	BLQ Values Included	0	0	0	0	0	0

PM3003537811

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 232 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.016	NA	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	2	3	5	1	3	4
	MEAN, GEO MEAN	12.618, 12.316	23.925, 18.098	19.402, 15.516	0.008, 0.008	0.022, 0.019	0.019, 0.015
	SD, SE	3.8757, 2.7405	22.3492, 12.9033	17.0839, 7.6401	NA, NA	0.0125, 0.0072	0.0124, 0.0062
	MEDIAN	12.618	12.774	12.774	0.008	0.026	0.017
	MIN, MAX	9.877, 15.358	9.346, 49.656	9.346, 49.656	0.008, 0.008	0.008, 0.032	0.008, 0.032
	5%, 95%	9.877, 15.358	9.346, 49.656	9.346, 49.656	NA, NA	0.008, 0.032	0.008, 0.032
	BLQ Values Included	0	0	0	0	0	0

PM3003537812

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC RACE
(Page 233 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.016	NA	0.016
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.016, 0.016	NA, NA	0.016, 0.016
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	14.405, 13.693	28.915, 22.609	21.660, 17.595	0.009, 0.009	0.020, 0.018	0.016, 0.013
	SD, SE	5.5050, 3.1783	25.4702, 14.7052	18.2969, 7.4697	0.0045, 0.0026	0.0111, 0.0056	0.0101, 0.0038
	MEDIAN	13.906	16.498	15.202	0.009	0.021	0.014
	MIN, MAX	9.166, 20.142	12.034, 58.212	9.166, 58.212	0.005, 0.014	0.008, 0.032	0.005, 0.032
	5%, 95%	9.166, 20.142	12.034, 58.212	9.166, 58.212	0.005, 0.014	0.008, 0.032	0.005, 0.032

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537813

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 234 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.002	NA	0.002
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.002, 0.002	NA, NA	0.002, 0.002
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	2.612, 2.451	5.688, 4.719	4.150, 3.401	0.002, 0.002	0.005, 0.003	0.003, 0.003
	SD, SE	1.1175, 0.6452	4.4121, 2.5473	3.3353, 1.3616	0.0010, 0.0006	0.0031, 0.0016	0.0026, 0.0010
	MEDIAN	2.479	3.554	3.151	0.002	0.005	0.003
	MIN, MAX	1.567, 3.790	2.748, 10.761	1.567, 10.761	0.001, 0.003	0.001, 0.008	0.001, 0.008
	5%, 95%	1.567, 3.790	2.748, 10.761	1.567, 10.761	0.001, 0.003	0.001, 0.008	0.001, 0.008
	BLQ Values Included	0	0	0	0	0	0

PM3003537814

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.004	NA	0.004
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.004, 0.004	NA, NA	0.004, 0.004
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	2	4	6
	MEAN, GEO MEAN	2.787, 2.650	6.386, 4.809	4.586, 3.570	0.003, 0.002	0.003, 0.003	0.003, 0.003
	SD, SE	1.0808, 0.6240	5.9789, 3.4519	4.3189, 1.7632	0.0007, 0.0005	0.0015, 0.0008	0.0013, 0.0005
	MEDIAN	2.588	3.504	3.046	0.003	0.003	0.003
	MIN, MAX	1.819, 3.953	2.394, 13.260	1.819, 13.260	0.002, 0.003	0.002, 0.005	0.002, 0.005
	5%, 95%	1.819, 3.953	2.394, 13.260	1.819, 13.260	0.002, 0.003	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	0	0	0

PM3003537815

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 236 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.003	NA	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	2	3	5	1	3	4
	MEAN, GEO MEAN	2.425, 2.367	4.598, 3.478	3.729, 2.982	0.002, 0.002	0.004, 0.004	0.004, 0.003
	SD, SE	0.7453, 0.5270	4.2957, 2.4801	3.2837, 1.4685	NA, NA	0.0021, 0.0012	0.0021, 0.0010
	MEDIAN	2.425	2.455	2.455	0.002	0.005	0.004
	MIN, MAX	1.898, 2.952	1.796, 9.544	1.796, 9.544	0.002, 0.002	0.002, 0.006	0.002, 0.006
	5%, 95%	1.898, 2.952	1.796, 9.544	1.796, 9.544	NA, NA	0.002, 0.006	0.002, 0.006
	BLQ Values Included	0	0	0	0	0	0

PM3003537816

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 237 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.003	NA	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.003, 0.003	NA, NA	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	2.769, 2.632	5.557, 4.346	4.163, 3.382	0.002, 0.002	0.004, 0.004	0.003, 0.003
	SD, SE	1.0587, 0.6113	4.8951, 2.8262	3.5166, 1.4356	0.0010, 0.0006	0.0018, 0.0009	0.0018, 0.0007
	MEDIAN	2.673	3.171	2.922	0.002	0.004	0.003
	MIN, MAX	1.761, 3.872	2.313, 11.188	1.761, 11.188	0.001, 0.003	0.002, 0.006	0.001, 0.006
	5%, 95%	1.761, 3.872	2.313, 11.188	1.761, 11.188	0.001, 0.003	0.002, 0.006	0.001, 0.006

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537817

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 238 of ?)

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	9.3, 9.3	NA, NA	9.3, 9.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	9.3	NA	9.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	9.3, 9.3	NA, NA	9.3, 9.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	1	1
	MEAN, GEO MEAN	3609.8, 1906.8	1593.8, 1512.8	2601.8, 1698.4	NA, NA	9.3, 9.3	9.3, 9.3
	SD, SE	4207.14, 2428.99	653.29, 377.18	2910.33, 1188.14	NA, NA	NA, NA	NA, NA
	MEDIAN	2052.5	1331.9	1692.2	NA	9.3	9.3
	MIN, MAX	403.4, 8373.6	1112.1, 2337.4	403.4, 8373.6	NA, NA	9.3, 9.3	9.3, 9.3
	5%, 95%	403.4, 8373.6	1112.1, 2337.4	403.4, 8373.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	NA	1	1

PM3003537818

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	4013.5, 3366.0	1742.3, 1662.4	2877.9, 2365.5	NA, NA	27.7, 20.7	27.7, 20.7
	SD, SE	2738.64, 1581.16	648.77, 374.57	2171.62, 886.56	NA, NA	25.95, 18.35	25.95, 18.35
	MEDIAN	3518.6	1648.3	2040.6	NA	27.7	27.7
	MIN, MAX	1556.0, 6965.8	1145.6, 2432.9	1145.6, 6965.8	NA, NA	9.3, 46.0	9.3, 46.0
	5%, 95%	1556.0, 6965.8	1145.6, 2432.9	1145.6, 6965.8	NA, NA	9.3, 46.0	9.3, 46.0
	BLQ Values Included	0	0	0	NA	2	2

PM3003537819

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 240 of 7)

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	2136.0, 1288.9	1660.5, 1587.1	1850.7, 1460.3	9.3, 9.3	9.3, 9.3	9.3, 9.3
	SD, SE	2408.76, 1703.25	640.98, 370.07	1312.92, 587.16	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	2136.0	1299.6	1299.6	9.3	9.3	9.3
	MIN, MAX	432.7, 3839.2	1281.4, 2400.6	432.7, 3839.2	9.3, 9.3	9.3, 9.3	9.3, 9.3
	5%, 95%	432.7, 3839.2	1281.4, 2400.6	432.7, 3839.2	9.3, 9.3	9.3, 9.3	9.3, 9.3
	BLQ Values Included	0	0	0	2	2	4

PM3003537820

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC RACE
(Page 241 of ?)

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	9.3, 9.3	NA, NA	9.3, 9.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	9.3	NA	9.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	9.3, 9.3	NA, NA	9.3, 9.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	3325.3, 2421.6	1665.5, 1590.4	2495.4, 1962.5	9.3, 9.3	13.4, 12.3	11.7, 11.0
	SD, SE	2836.52, 1637.67	639.69, 369.33	2051.46, 837.50	0.00, 0.00	7.04, 4.07	5.46, 2.44
	MEDIAN	2785.6	1426.6	1908.5	9.3	9.3	9.3
	MIN, MAX	797.4, 6392.9	1179.7, 2390.3	797.4, 6392.9	9.3, 9.3	9.3, 21.5	9.3, 21.5
	5%, 95%	797.4, 6392.9	1179.7, 2390.3	797.4, 6392.9	9.3, 9.3	9.3, 21.5	9.3, 21.5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537821

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	27.900, 27.900	NA, NA	27.900, 27.900
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	27.900	NA	27.900
	MIN, MAX	NA, NA	NA, NA	NA, NA	27.900, 27.900	NA, NA	27.900, 27.900
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	1	1
	MEAN, GEO MEAN	3712.730, 2363.770	3729.770, 3457.330	3721.250, 2858.730	NA, NA	11.160, 11.160	11.160, 11.160
	SD, SE	3386.7000, 1955.3100	1798.4400, 1038.3300	2425.2300, 990.0960	NA, NA	NA, NA	NA, NA
	MEDIAN	3304.530	3225.090	3264.810	NA	11.160	11.160
	MIN, MAX	548.624, 7285.032	2237.592, 5726.630	548.624, 7285.032	NA, NA	11.160, 11.160	11.160, 11.160
	5%, 95%	548.624, 7285.030	2237.590, 5726.630	548.624, 7285.030	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	NA	1	1

PM3003537822

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 243 of ?)

Lab: INBIFO
Biomarker: Nicotine Glurunonide (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	4306.240, 4043.740	4015.240, 3928.440	4160.740, 3985.670	NA, NA	39.730, 38.893	39.730, 38.893
	SD, SE	1923.8500, 1110.7300	1062.4300, 613.3960	1399.0600, 571.1660	NA, NA	11.4693, 8.1100	11.4693, 8.1100
	MEDIAN	3624.160	3551.360	3587.760	NA	39.730	39.730
	MIN, MAX	2816.360, 6478.194	3263.634, 5230.735	2816.360, 6478.194	NA, NA	31.620, 47.840	31.620, 47.840
	5%, 95%	2816.360, 6478.190	3263.630, 5230.740	2816.360, 6478.190	NA, NA	31.620, 47.840	31.620, 47.840
	BLQ Values Included	0	0	0	NA	2	2

PM3003537823

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 244 of 7)

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	3273.940, 1885.030	3447.030, 3209.520	3377.800, 2594.130	17.968, 17.926	20.739, 18.674	19.353, 18.296
	SD, SE	3785.5900, 2676.8200	1583.0300, 913.9650	2201.0600, 984.3430	1.7359, 1.2275	12.7576, 9.0210	7.6038, 3.8019
	MEDIAN	3273.940	3139.430	3139.430	17.968	20.739	17.968
	MIN, MAX	597.126, 5950.760	2040.372, 5161.290	597.126, 5950.760	16.740, 19.195	11.718, 29.760	11.718, 29.760
	5%, 95%	597.126, 5950.760	2040.370, 5161.290	597.126, 5950.760	16.740, 19.195	11.718, 29.760	11.718, 29.760
	BLQ Values Included	0	0	0	2	2	4

PM3003537824

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Nicotine Glurunonide (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	27.900, 27.900	NA, NA	27.900, 27.900
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	27.900	NA	27.900
	MIN, MAX	NA, NA	NA, NA	NA, NA	27.900, 27.900	NA, NA	27.900, 27.900
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	3785.460, 3109.510	3730.680, 3547.480	3758.070, 3321.290	17.968, 17.926	28.318, 28.098	24.178, 23.474
	SD, SE	2640.0000, 1524.2100	1476.2200, 852.2950	1913.2300, 781.0710	1.7359, 1.2275	4.2129, 2.4323	6.4626, 2.8902
	MEDIAN	3464.340	3305.290	3384.820	17.968	29.760	23.573
	MIN, MAX	1320.700, 6571.330	2513.870, 5372.890	1320.700, 6571.330	16.740, 19.195	23.573, 31.620	16.740, 31.620
	5%, 95%	1320.700, 6571.330	2513.870, 5372.890	1320.700, 6571.330	16.740, 19.195	23.573, 31.620	16.740, 31.620

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537825

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.011, 0.011	NA, NA	0.011, 0.011
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.011	NA	0.011
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.011, 0.011	NA, NA	0.011, 0.011
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	1	1
	MEAN, GEO MEAN	2.478, 1.628	3.022, 2.636	2.750, 2.071	NA, NA	0.014, 0.014	0.014, 0.014
	SD, SE	2.3928, 1.3815	1.6021, 0.9250	1.8455, 0.7534	NA, NA	NA, NA	NA, NA
	MEDIAN	1.864	3.809	2.837	NA	0.014	0.014
	MIN, MAX	0.452, 5.118	1.179, 4.079	0.452, 5.118	NA, NA	0.014, 0.014	0.014, 0.014
	5%, 95%	0.452, 5.118	1.179, 4.079	0.452, 5.118	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	NA	1	1

PM3003537826

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	3.716, 3.439	2.965, 2.868	3.341, 3.141	NA, NA	0.036, 0.036	0.036, 0.036
	SD, SE	1.8604, 1.0741	0.8736, 0.5044	1.3634, 0.5566	NA, NA	0.0042, 0.0030	0.0042, 0.0030
	MEDIAN	2.941	3.310	3.126	NA	0.036	0.036
	MIN, MAX	2.369, 5.839	1.972, 3.614	1.972, 5.839	NA, NA	0.033, 0.039	0.033, 0.039
	5%, 95%	2.369, 5.839	1.972, 3.614	1.972, 5.839	NA, NA	0.033, 0.039	0.033, 0.039
	BLQ Values Included	0	0	0	NA	2	2

PM3003537827

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: INBIFO
Biomarker: Nicotine Glucuronide (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	2.936, 2.263	3.107, 2.733	3.039, 2.535	0.015, 0.014	0.015, 0.014	0.015, 0.014
	SD, SE	2.6439, 1.8695	1.7805, 1.0280	1.8280, 0.8175	0.0057, 0.0040	0.0085, 0.0060	0.0059, 0.0029
	MEDIAN	2.936	3.022	3.022	0.015	0.015	0.015
	MIN, MAX	1.066, 4.805	1.371, 4.929	1.066, 4.929	0.011, 0.019	0.009, 0.021	0.009, 0.021
	5%, 95%	1.066, 4.805	1.371, 4.929	1.066, 4.929	0.011, 0.019	0.009, 0.021	0.009, 0.021
	BLQ Values Included	0	0	0	2	2	4

PM3003537828

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.011, 0.011	NA, NA	0.011, 0.011
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.011	NA	0.011
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.011, 0.011	NA, NA	0.011, 0.011
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	2.952, 2.547	3.032, 2.783	2.992, 2.662	0.015, 0.014	0.025, 0.024	0.021, 0.020
	SD, SE	2.0181, 1.1652	1.3568, 0.7833	1.5386, 0.6281	0.0057, 0.0040	0.0069, 0.0040	0.0079, 0.0035
	MEDIAN	2.117	3.482	2.800	0.015	0.021	0.021
	MIN, MAX	1.486, 5.254	1.507, 4.106	1.486, 5.254	0.011, 0.019	0.021, 0.033	0.011, 0.033
	5%, 95%	1.486, 5.254	1.507, 4.106	1.486, 5.254	0.011, 0.019	0.021, 0.033	0.011, 0.033

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537829

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	23.700, 23.700	NA, NA	23.700, 23.700
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	23.700	NA	23.700
	MIN, MAX	NA, NA	NA, NA	NA, NA	23.700, 23.700	NA, NA	23.700, 23.700
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	2	2	4
	MEAN, GEO MEAN	13071.900, 6498.190	13773.200, 13119.300	13422.600, 9233.170	13.904, 13.727	17.412, 15.500	15.658, 14.587
	SD, SE	11737.1000, 6776.4200	5506.3000, 3179.0700	8208.4800, 3351.1000	3.1282, 2.2120	11.2168, 7.9315	7.0215, 3.5108
	MEDIAN	14233.800	10987.200	12610.500	13.904	17.412	13.904
	MIN, MAX	797.096, 24184.869	10216.584, 20115.725	797.096, 24184.869	11.692, 16.116	9.480, 25.343	9.480, 25.343
	5%, 95%	797.096, 24184.900	10216.600, 20115.700	797.096, 24184.900	11.692, 16.116	9.480, 25.343	9.480, 25.343
	BLQ Values Included	0	0	0	2	2	4

PM3003537830

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	21.725, 21.725	NA, NA	21.725, 21.725
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	21.725	NA	21.725
	MIN, MAX	NA, NA	NA, NA	NA, NA	21.725, 21.725	NA, NA	21.725, 21.725
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	12636.600, 8989.660	13934.500, 13447.500	13285.500, 10994.900	16.485, 15.921	19.263, 17.114	17.874, 16.507
	SD, SE	9131.5200, 5272.0800	4577.3700, 2642.7400	6499.2400, 2653.3000	5.5645, 3.2127	9.7891, 5.6517	7.2823, 2.9730
	MEDIAN	15906.200	13037.400	14471.800	13.272	22.713	17.993
	MIN, MAX	2320.420, 19683.264	9872.082, 18893.985	2320.420, 19683.264	13.272, 22.910	8.216, 26.860	8.216, 26.860
	5%, 95%	2320.420, 19683.300	9872.080, 18894.000	2320.420, 19683.300	13.272, 22.910	8.216, 26.860	8.216, 26.860
	BLQ Values Included	0	0	0	3	3	6

PM3003537831

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 252 of ?)

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	9852.460, 2562.480	11811.600, 11287.300	11027.900, 6237.610	17.812, 17.448	12.140, 11.974	14.976, 14.454
	SD, SE	13454.0000, 9513.3900	4052.3300, 2339.6200	7390.1600, 3304.9800	4.5365, 2.6192	2.4911, 1.4382	4.5130, 1.8424
	MEDIAN	9852.460	12845.600	12845.600	16.306	11.613	14.536
	MIN, MAX	339.066, 19365.855	7342.419, 15246.725	339.066, 19365.855	14.220, 22.910	9.954, 14.852	9.954, 22.910
	5%, 95%	339.066, 19365.900	7342.420, 15246.700	339.066, 19365.900	14.220, 22.910	9.954, 14.852	9.954, 22.910
	BLQ Values Included	0	0	0	3	3	6

PM3003537832

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 253 of ?)

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	22.713, 22.713	NA, NA	22.713, 22.713
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	22.713	NA	22.713
	MIN, MAX	NA, NA	NA, NA	NA, NA	22.713, 22.713	NA, NA	22.713, 22.713
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	12433.400, 7153.010	13173.100, 12666.900	12803.200, 9518.730	16.165, 16.033	16.429, 15.218	16.316, 15.562
	SD, SE	10221.2000, 5901.2200	4535.8300, 2618.7600	7083.9900, 2892.0300	2.6061, 1.5046	7.1309, 3.5655	5.2639, 1.9896
	MEDIAN	15070.000	12290.100	13680.100	14.789	16.235	14.789
	MIN, MAX	1152.190, 21078.000	9143.700, 18085.500	1152.190, 21078.000	14.536, 19.171	9.217, 24.028	9.217, 24.028
	5%, 95%	1152.190, 21078.000	9143.700, 18085.500	1152.190, 21078.000	14.536, 19.171	9.217, 24.028	9.217, 24.028

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537833

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Cotinine Glurunoide (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.009, 0.009	NA, NA	0.009, 0.009
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.009	NA	0.009
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.009, 0.009	NA, NA	0.009, 0.009
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	2	2	4
	MEAN, GEO MEAN	8.559, 4.473	10.895, 10.002	9.727, 6.689	0.010, 0.009	0.019, 0.017	0.014, 0.013
	SD, SE	8.1809, 4.7232	4.8224, 2.7842	6.1408, 2.5070	0.0035, 0.0025	0.0092, 0.0065	0.0077, 0.0039
	MEDIAN	8.030	12.975	10.503	0.010	0.019	0.012
	MIN, MAX	0.656, 16.992	5.382, 14.329	0.656, 16.992	0.007, 0.012	0.012, 0.025	0.007, 0.025
	5%, 95%	0.656, 16.992	5.382, 14.329	0.656, 16.992	0.007, 0.012	0.012, 0.025	0.007, 0.025
	BLQ Values Included	0	0	0	2	2	4

PM3003537834

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.010, 0.010	NA, NA	0.010, 0.010
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.010	NA	0.010
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.010, 0.010	NA, NA	0.010, 0.010
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	10.188, 7.646	10.396, 9.817	10.292, 8.664	0.010, 0.009	0.017, 0.015	0.014, 0.012
	SD, SE	7.6612, 4.4232	3.8935, 2.2479	5.4364, 2.2194	0.0056, 0.0032	0.0105, 0.0061	0.0085, 0.0035
	MEDIAN	10.399	11.956	11.178	0.009	0.017	0.013
	MIN, MAX	2.423, 17.741	5.964, 13.267	2.423, 17.741	0.005, 0.016	0.007, 0.028	0.005, 0.028
	5%, 95%	2.423, 17.741	5.964, 13.267	2.423, 17.741	0.005, 0.016	0.007, 0.028	0.005, 0.028
	BLQ Values Included	0	0	0	3	3	6

PM3003537835

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	8.121, 3.076	10.620, 9.613	9.621, 6.094	0.013, 0.013	0.013, 0.012	0.013, 0.013
	SD, SE	10.6292, 7.5160	5.0463, 2.9135	6.5461, 2.9275	0.0038, 0.0022	0.0044, 0.0025	0.0037, 0.0015
	MEDIAN	8.121	12.366	12.366	0.015	0.015	0.015
	MIN, MAX	0.605, 15.637	4.933, 14.562	0.605, 15.637	0.009, 0.016	0.008, 0.016	0.008, 0.016
	5%, 95%	0.605, 15.637	4.933, 14.562	0.605, 15.637	0.009, 0.016	0.008, 0.016	0.008, 0.016
	BLQ Values Included	0	0	0	3	3	6

PM3003537836

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.010, 0.010	NA, NA	0.010, 0.010
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.010	NA	0.010
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.010, 0.010	NA, NA	0.010, 0.010
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	9.078, 5.749	10.637, 9.833	9.857, 7.519	0.011, 0.010	0.017, 0.016	0.014, 0.013
	SD, SE	7.7819, 4.4929	4.5283, 2.6144	5.7580, 2.3507	0.0032, 0.0019	0.0059, 0.0030	0.0057, 0.0022
	MEDIAN	9.215	12.869	11.042	0.012	0.019	0.013
	MIN, MAX	1.228, 16.790	5.426, 13.616	1.228, 16.790	0.007, 0.013	0.009, 0.022	0.007, 0.022
	5%, 95%	1.228, 16.790	5.426, 13.616	1.228, 16.790	0.007, 0.013	0.009, 0.022	0.007, 0.022

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537837

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 258 of ?)

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	7.9, 7.9	NA, NA	7.9, 7.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	7.9	NA	7.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	7.9, 7.9	NA, NA	7.9, 7.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	2	2	4
	MEAN, GEO MEAN	12408.6, 5242.0	6026.8, 5740.5	9217.7, 5485.6	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	13952.70, 8055.59	2211.40, 1276.75	9594.01, 3916.74	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	8840.9	6081.3	7145.9	7.9	7.9	7.9
	MIN, MAX	586.1, 27798.7	3788.7, 8210.5	586.1, 27798.7	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	586.1, 27798.7	3788.7, 8210.5	586.1, 27798.7	7.9, 7.9	7.9, 7.9	7.9, 7.9
	BLQ Values Included	0	0	0	2	2	4

PM3003537838

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 259 of ?)

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	7.9, 7.9	NA, NA	7.9, 7.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	7.9	NA	7.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	7.9, 7.9	NA, NA	7.9, 7.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	12629.9, 7483.0	5993.1, 5690.5	9311.5, 6525.5	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	10235.50, 5909.49	2451.58, 1415.42	7584.50, 3096.36	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	15442.9	4985.9	6886.9	7.9	7.9	7.9
	MIN, MAX	1282.0, 21164.8	4205.6, 8787.9	1282.0, 21164.8	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	1282.0, 21164.8	4205.6, 8787.9	1282.0, 21164.8	7.9, 7.9	7.9, 7.9	7.9, 7.9
	BLQ Values Included	0	0	0	3	3	6

PM3003537839

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 260 of ?)

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	6369.9, 1752.1	5670.4, 5581.6	5950.2, 3511.4	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	8660.93, 6124.20	1262.84, 729.10	4438.14, 1984.80	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	6369.9	5243.1	5243.1	7.9	7.9	7.9
	MIN, MAX	245.7, 12494.1	4676.7, 7091.5	245.7, 12494.1	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	245.7, 12494.1	4676.7, 7091.5	245.7, 12494.1	7.9, 7.9	7.9, 7.9	7.9, 7.9
	BLQ Values Included	0	0	0	3	3	6

PM3003537840

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	7.9, 7.9	NA, NA	7.9, 7.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	7.9	NA	7.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	7.9, 7.9	NA, NA	7.9, 7.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	11110.8, 5596.2	5896.8, 5707.7	8503.8, 5651.7	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	9930.88, 5733.59	1894.02, 1093.51	7002.82, 2858.89	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	12141.9	5248.0	6639.0	7.9	7.9	7.9
	MIN, MAX	704.6, 20485.9	4412.5, 8030.0	704.6, 20485.9	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	704.6, 20485.9	4412.5, 8030.0	704.6, 20485.9	7.9, 7.9	7.9, 7.9	7.9, 7.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537841

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 262 of 7)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	2967.6, 2577.2	3491.0, 3364.4	3229.3, 2944.6	12.6, 12.6	23.5, 23.5	18.1, 17.2
	SD, SE	1587.37, 916.47	1069.44, 617.44	1244.01, 507.87	NA, NA	NA, NA	7.71, 5.45
	MEDIAN	3869.9	4093.9	3884.0	12.6	23.5	18.1
	MIN, MAX	1134.7, 3898.1	2256.2, 4122.8	1134.7, 4122.8	12.6, 12.6	23.5, 23.5	12.6, 23.5
	5%, 95%	1134.7, 3898.1	2256.2, 4122.8	1134.7, 4122.8	NA, NA	NA, NA	12.6, 23.5
	BLQ Values Included	0	0	0	0	0	0

PM3003537842

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 263 of ?)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	0	1
	MEAN, GEO MEAN	5047.3, 4630.8	2475.6, 2404.6	3761.5, 3336.9	14.3, 14.3	NA, NA	14.3, 14.3
	SD, SE	2322.19, 1340.72	758.18, 437.73	2090.68, 853.52	NA, NA	NA, NA	NA, NA
	MEDIAN	5439.6	2146.2	2948.4	14.3	NA	14.3
	MIN, MAX	2553.9, 7148.3	1937.9, 3342.8	1937.9, 7148.3	14.3, 14.3	NA, NA	14.3, 14.3
	5%, 95%	2553.9, 7148.3	1937.9, 3342.8	1937.9, 7148.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	0	NA	0

PM3003537843

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 264 of ?)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	0	0	0
	MEAN, GEO MEAN	1746.4, 932.8	2906.2, 1703.6	2442.3, 1338.9	NA, NA	NA, NA	NA, NA
	SD, SE	2087.94, 1476.40	3474.95, 2006.26	2744.27, 1227.28	NA, NA	NA, NA	NA, NA
	MEDIAN	1746.4	1240.5	1240.5	NA	NA	NA
	MIN, MAX	270.0, 3222.8	577.6, 6900.4	270.0, 6900.4	NA, NA	NA, NA	NA, NA
	5%, 95%	270.0, 3222.8	577.6, 6900.4	270.0, 6900.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	NA	NA	NA

PM3003537844

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 265 of 7)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3671.8, 3122.2	2957.6, 2709.5	3314.7, 2908.5	13.5, 13.5	23.5, 23.5	18.5, 17.8
	SD, SE	2141.75, 1236.54	1586.08, 915.72	1730.35, 706.41	NA, NA	NA, NA	7.07, 5.00
	MEDIAN	4186.8	2212.8	3199.8	13.5	23.5	18.5
	MIN, MAX	1319.5, 5509.1	1881.0, 4779.0	1319.5, 5509.1	13.5, 13.5	23.5, 23.5	13.5, 23.5
	5%, 95%	1319.5, 5509.1	1881.0, 4779.0	1319.5, 5509.1	NA, NA	NA, NA	13.5, 23.5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537845

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 266 of ?)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3721.690, 3194.770	8108.770, 7688.830	5915.230, 4956.210	16.758, 16.758	76.375, 76.375	46.567, 35.776
	SD, SE	2361.0700, 1363.1600	3333.5000, 1924.6000	3528.2700, 1440.4100	NA, NA	NA, NA	42.1556, 29.8085
	MEDIAN	3391.350	6926.300	5879.110	16.758	76.375	46.567
	MIN, MAX	1543.192, 6230.539	5527.690, 11872.310	1543.192, 11872.310	16.758, 16.758	76.375, 76.375	16.758, 76.375
	5%, 95%	1543.190, 6230.540	5527.690, 11872.300	1543.190, 11872.300	NA, NA	NA, NA	16.758, 76.375
	BLQ Values Included	0	0	0	0	0	0

PM3003537846

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	0	1
	MEAN, GEO MEAN	5681.380, 5563.190	6271.350, 5682.320	5976.360, 5622.440	24.024, 24.024	NA, NA	24.024, 24.024
	SD, SE	1472.3600, 850.0660	3564.4500, 2057.9300	2460.4200, 1004.4600	NA, NA	NA, NA	NA, NA
	MEDIAN	5058.830	4614.330	4840.690	24.024	NA	24.024
	MIN, MAX	4622.559, 7362.749	3837.042, 10362.680	3837.042, 10362.680	24.024, 24.024	NA, NA	24.024, 24.024
	5%, 95%	4622.560, 7362.750	3837.040, 10362.700	3837.040, 10362.700	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	0	NA	0

PM3003537847

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 268 of 7)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	0	0	0
	MEAN, GEO MEAN	2683.970, 1364.280	6826.630, 3445.090	5169.570, 2378.380	NA, NA	NA, NA	NA, NA
	SD, SE	3268.7700, 2311.3700	8773.2300, 5065.2300	6804.7400, 3043.1700	NA, NA	NA, NA	NA, NA
	MEDIAN	2683.970	2667.080	2667.080	NA	NA	NA
	MIN, MAX	372.600, 4995.340	906.832, 16905.980	372.600, 16905.980	NA, NA	NA, NA	NA, NA
	5%, 95%	372.600, 4995.340	906.832, 16906.000	372.600, 16906.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	NA	NA	NA

PM3003537848

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	4485.980, 4049.170	7068.920, 6006.500	5777.450, 4931.670	20.391, 20.391	76.375, 76.375	48.383, 39.463
	SD, SE	2308.6000, 1332.8700	5180.6500, 2991.0500	3856.0300, 1574.2200	NA, NA	NA, NA	39.5867, 27.9920
	MEDIAN	4481.840	4269.700	4375.770	20.391	76.375	48.383
	MIN, MAX	2179.450, 6796.640	3890.060, 13047.000	2179.450, 13047.000	20.391, 20.391	76.375, 76.375	20.391, 76.375
	5%, 95%	2179.450, 6796.640	3890.060, 13047.000	2179.450, 13047.000	NA, NA	NA, NA	20.391, 76.375

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537849

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 270 of ?)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	2.390, 2.200	7.202, 5.862	4.796, 3.591	0.007, 0.007	0.055, 0.055	0.031, 0.020
	SD, SE	1.1220, 0.6478	5.9063, 3.4100	4.6266, 1.8888	NA, NA	NA, NA	0.0339, 0.0240
	MEDIAN	2.383	3.938	3.582	0.007	0.055	0.031
	MIN, MAX	1.271, 3.515	3.648, 14.020	1.271, 14.020	0.007, 0.007	0.055, 0.055	0.007, 0.055
	5%, 95%	1.271, 3.515	3.648, 14.020	1.271, 14.020	NA, NA	NA, NA	0.007, 0.055
	BLQ Values Included	0	0	0	0	0	0

PM3003537850

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 271 of ?)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	0	1
	MEAN, GEO MEAN	4.734, 4.732	5.261, 4.148	4.998, 4.431	0.009, 0.009	NA, NA	0.009, 0.009
	SD, SE	0.1509, 0.0871	4.5860, 2.6477	2.9163, 1.1906	NA, NA	NA, NA	NA, NA
	MEDIAN	4.814	2.920	4.687	0.009	NA	0.009
	MIN, MAX	4.560, 4.828	2.318, 10.545	2.318, 10.545	0.009, 0.009	NA, NA	0.009, 0.009
	5%, 95%	4.560, 4.828	2.318, 10.545	2.318, 10.545	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	0	NA	0

PM3003537851

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 272 of ?)

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	0	0	0
	MEAN, GEO MEAN	2.350, 1.638	6.477, 2.934	4.826, 2.324	NA, NA	NA, NA	NA, NA
	SD, SE	2.3822, 1.6845	8.5405, 4.9308	6.5574, 2.9326	NA, NA	NA, NA	NA, NA
	MEDIAN	2.350	2.547	2.547	NA	NA	NA
	MIN, MAX	0.665, 4.034	0.609, 16.275	0.609, 16.275	NA, NA	NA, NA	NA, NA
	5%, 95%	0.665, 4.034	0.609, 16.275	0.609, 16.275	NA, NA	NA, NA	NA, NA
	BLQ Values Included	0	0	0	NA	NA	NA

PM3003537852

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3.360, 3.251	6.313, 4.540	4.837, 3.842	0.008, 0.008	0.055, 0.055	0.032, 0.021
	SD, SE	0.9896, 0.5713	6.3393, 3.6600	4.3685, 1.7834	NA, NA	NA, NA	0.0332, 0.0235
	MEDIAN	3.659	3.135	3.397	0.008	0.055	0.032
	MIN, MAX	2.255, 4.165	2.192, 13.613	2.192, 13.613	0.008, 0.008	0.055, 0.055	0.008, 0.055
	5%, 95%	2.255, 4.165	2.192, 13.613	2.192, 13.613	NA, NA	NA, NA	0.008, 0.055

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537853

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Total NNAL (pg/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	677.7, 677.7	677.7, 677.7	7.0, 7.0	6.0, 6.0	6.3, 6.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.58, 0.33
	MEDIAN	NA	677.7	677.7	7.0	6.0	6.0
	MIN, MAX	NA, NA	677.7, 677.7	677.7, 677.7	7.0, 7.0	6.0, 6.0	6.0, 7.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 7.0
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	28	45	28	33	61
	MEAN, GEO MEAN	532.4, 308.3	575.8, 379.7	559.4, 351.0	14.2, 7.6	6.0, 6.0	9.8, 6.7
	SD, SE	500.33, 121.35	474.72, 89.71	479.34, 71.46	34.51, 6.52	0.17, 0.03	23.51, 3.01
	MEDIAN	445.5	484.0	475.2	6.0	6.0	6.0
	MIN, MAX	6.0, 1773.9	13.5, 2045.7	6.0, 2045.7	6.0, 185.7	6.0, 7.0	6.0, 185.7
	5%, 95%	6.0, 1773.9	16.5, 1604.2	16.5, 1604.2	6.0, 47.3	6.0, 6.0	6.0, 8.8
	BLQ Values Included	1	0	1	23	32	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.0	6.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	313.4, 178.1	313.4, 178.1	6.0, 6.0	NA, NA	6.0, 6.0
	SD, SE	NA, NA	359.06, 207.31	359.06, 207.31	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	174.0	174.0	6.0	NA	6.0
	MIN, MAX	NA, NA	45.0, 721.3	45.0, 721.3	6.0, 6.0	NA, NA	6.0, 6.0
	5%, 95%	NA, NA	45.0, 721.3	45.0, 721.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537854

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 275 of ?)

Lab: Madison
Biomarker: Total NNAL (pg/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	695.2, 695.2	695.2, 695.2	6.0, 6.0	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	695.2	695.2	6.0	6.0	6.0
	MIN, MAX	NA, NA	695.2, 695.2	695.2, 695.2	6.0, 6.0	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	427.5, 286.6	660.2, 449.1	566.0, 374.5	7.7, 6.6	7.3, 6.7	7.5, 6.6
	SD, SE	313.45, 76.02	583.57, 116.71	501.05, 77.31	7.80, 1.47	4.88, 0.85	6.33, 0.81
	MEDIAN	415.9	482.0	426.6	6.0	6.0	6.0
	MIN, MAX	6.0, 1235.3	30.5, 2223.3	6.0, 2223.3	6.0, 47.3	6.0, 31.4	6.0, 47.3
	5%, 95%	6.0, 1235.3	53.0, 1842.9	53.0, 1721.9	6.0, 8.6	6.0, 17.7	6.0, 11.9
	BLQ Values Included	1	0	1	24	30	54
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.0	6.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	320.7, 232.4	320.7, 232.4	6.0, 6.0	NA, NA	6.0, 6.0
	SD, SE	NA, NA	320.52, 185.05	320.52, 185.05	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	153.3	153.3	6.0	NA	6.0
	MIN, MAX	NA, NA	118.6, 690.3	118.6, 690.3	6.0, 6.0	NA, NA	6.0, 6.0
	5%, 95%	NA, NA	118.6, 690.3	118.6, 690.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537855

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Total NNAL (pg/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	686.5, 686.5	686.5, 686.5	6.5, 6.5	6.0, 6.0	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.29, 0.17
	MEDIAN	NA	686.5	686.5	6.5	6.0	6.0
	MIN, MAX	NA, NA	686.5, 686.5	686.5, 686.5	6.5, 6.5	6.0, 6.0	6.0, 6.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.5
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	486.9, 321.5	597.2, 412.5	554.0, 374.2	10.9, 7.4	6.7, 6.4	8.6, 6.9
	SD, SE	362.20, 85.37	477.77, 90.29	435.29, 64.18	18.38, 3.47	2.44, 0.42	12.64, 1.62
	MEDIAN	385.6	453.3	433.9	6.0	6.0	6.0
	MIN, MAX	6.0, 1230.7	22.0, 1663.1	6.0, 1663.1	6.0, 95.9	6.0, 18.7	6.0, 95.9
	5%, 95%	6.0, 1230.7	34.8, 1653.7	34.8, 1471.5	6.0, 47.3	6.0, 11.9	6.0, 11.9
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.0	6.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	317.1, 211.4	317.1, 211.4	6.0, 6.0	NA, NA	6.0, 6.0
	SD, SE	NA, NA	339.11, 195.78	339.11, 195.78	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	163.7	163.7	6.0	NA	6.0
	MIN, MAX	NA, NA	81.8, 705.8	81.8, 705.8	6.0, 6.0	NA, NA	6.0, 6.0
	5%, 95%	NA, NA	81.8, 705.8	81.8, 705.8	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537856

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Total NNAL (pmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3239.4, 3239.4	3239.4, 3239.4	33.5, 33.5	28.7, 28.7	30.3, 30.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	2.77, 1.60
	MEDIAN	NA	3239.4	3239.4	33.5	28.7	28.7
	MIN, MAX	NA, NA	3239.4, 3239.4	3239.4, 3239.4	33.5, 33.5	28.7, 28.7	28.7, 33.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 33.5
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	28	45	28	33	61
	MEAN, GEO MEAN	2544.7, 1473.7	2752.4, 1815.0	2674.0, 1677.6	67.7, 36.3	28.8, 28.8	46.7, 32.0
	SD, SE	2391.57, 580.04	2269.15, 428.83	2291.26, 341.56	164.94, 31.17	0.84, 0.15	112.36, 14.39
	MEDIAN	2129.5	2313.3	2271.5	28.7	28.7	28.7
	MIN, MAX	28.7, 8479.2	64.5, 9778.4	28.7, 9778.4	28.7, 887.6	28.7, 33.5	28.7, 887.6
	5%, 95%	28.7, 8479.2	78.9, 7668.1	78.9, 7668.1	28.7, 226.1	28.7, 28.7	28.7, 42.1
	BLQ Values Included	1	0	1	23	32	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.7	28.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1498.2, 851.2	1498.2, 851.2	28.7, 28.7	NA, NA	28.7, 28.7
	SD, SE	NA, NA	1716.32, 990.92	1716.32, 990.92	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	831.7	831.7	28.7	NA	28.7
	MIN, MAX	NA, NA	215.1, 3447.8	215.1, 3447.8	28.7, 28.7	NA, NA	28.7, 28.7
	5%, 95%	NA, NA	215.1, 3447.8	215.1, 3447.8	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537857

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Total NNAL (pmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3323.1, 3323.1	3323.1, 3323.1	28.7, 28.7	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	3323.1	3323.1	28.7	28.7	28.7
	MIN, MAX	NA, NA	3323.1, 3323.1	3323.1, 3323.1	28.7, 28.7	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	2043.4, 1370.0	3155.8, 2146.8	2705.5, 1789.9	36.6, 31.7	34.9, 31.8	35.7, 31.8
	SD, SE	1498.29, 363.39	2789.45, 557.89	2395.05, 369.56	37.26, 7.04	23.30, 4.06	30.25, 3.87
	MEDIAN	1988.0	2304.0	2038.9	28.7	28.7	28.7
	MIN, MAX	28.7, 5904.7	145.8, 10627.4	28.7, 10627.4	28.7, 226.1	28.7, 150.1	28.7, 226.1
	5%, 95%	28.7, 5904.7	253.3, 8809.1	253.3, 8230.7	28.7, 41.1	28.7, 84.6	28.7, 56.9
	BLQ Values Included	1	0	1	24	30	54
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.7	28.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1533.1, 1110.8	1533.1, 1110.8	28.7, 28.7	NA, NA	28.7, 28.7
	SD, SE	NA, NA	1532.08, 884.55	1532.08, 884.55	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	732.8	732.8	28.7	NA	28.7
	MIN, MAX	NA, NA	566.9, 3299.6	566.9, 3299.6	28.7, 28.7	NA, NA	28.7, 28.7
	5%, 95%	NA, NA	566.9, 3299.6	566.9, 3299.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537858

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 279 of ?)

Lab: Madison
Biomarker: Total NNAL (pmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3281.3, 3281.3	3281.3, 3281.3	31.1, 31.1	28.7, 28.7	29.5, 29.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	1.39, 0.80
	MEDIAN	NA	3281.3	3281.3	31.1	28.7	28.7
	MIN, MAX	NA, NA	3281.3, 3281.3	3281.3, 3281.3	31.1, 31.1	28.7, 28.7	28.7, 31.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 31.1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2327.4, 1536.6	2854.3, 1971.8	2648.1, 1788.5	52.2, 35.3	31.9, 30.8	41.2, 32.8
	SD, SE	1731.30, 408.07	2283.71, 431.58	2080.66, 306.78	87.81, 16.60	11.64, 2.03	60.38, 7.73
	MEDIAN	1843.1	2166.6	2074.0	28.7	28.7	28.7
	MIN, MAX	28.7, 5882.5	105.2, 7949.4	28.7, 7949.4	28.7, 458.2	28.7, 89.4	28.7, 458.2
	5%, 95%	28.7, 5882.5	166.1, 7904.4	166.1, 7033.6	28.7, 226.1	28.7, 56.7	28.7, 56.7
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.7	28.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1515.7, 1010.5	1515.7, 1010.5	28.7, 28.7	NA, NA	28.7, 28.7
	SD, SE	NA, NA	1620.95, 935.86	1620.95, 935.86	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	782.3	782.3	28.7	NA	28.7
	MIN, MAX	NA, NA	391.0, 3373.7	391.0, 3373.7	28.7, 28.7	NA, NA	28.7, 28.7
	5%, 95%	NA, NA	391.0, 3373.7	391.0, 3373.7	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537859

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 280 of ?)

Lab: Madison
Biomarker: Free NNAL (pg/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	249.9, 249.9	249.9, 249.9	6.0, 6.0	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	249.9	249.9	6.0	6.0	6.0
	MIN, MAX	NA, NA	249.9, 249.9	249.9, 249.9	6.0, 6.0	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	121.7, 84.9	163.9, 119.8	147.4, 104.7	6.5, 6.3	6.3, 6.2	6.4, 6.3
	SD, SE	83.64, 19.71	115.27, 21.78	105.11, 15.50	2.70, 0.51	0.96, 0.17	1.95, 0.25
	MEDIAN	127.5	150.8	136.4	6.0	6.0	6.0
	MIN, MAX	6.0, 333.0	6.0, 484.5	6.0, 484.5	6.0, 20.3	6.0, 9.6	6.0, 20.3
	5%, 95%	6.0, 333.0	11.4, 463.9	11.4, 333.0	6.0, 6.0	6.0, 9.6	6.0, 8.5
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.0	6.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	157.9, 102.9	157.9, 102.9	6.0, 6.0	NA, NA	6.0, 6.0
	SD, SE	NA, NA	167.01, 96.42	167.01, 96.42	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	91.7	91.7	6.0	NA	6.0
	MIN, MAX	NA, NA	34.2, 347.9	34.2, 347.9	6.0, 6.0	NA, NA	6.0, 6.0
	5%, 95%	NA, NA	34.2, 347.9	34.2, 347.9	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 281 of ?)

Lab: Madison
Biomarker: Free NNAL (pg/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	280.4, 280.4	280.4, 280.4	6.0, 6.0	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	280.4	280.4	6.0	6.0	6.0
	MIN, MAX	NA, NA	280.4, 280.4	280.4, 280.4	6.0, 6.0	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	122.7, 89.1	185.1, 153.0	159.8, 122.9	8.9, 7.1	6.1, 6.1	7.4, 6.6
	SD, SE	81.19, 19.69	117.92, 23.58	108.04, 16.67	9.44, 1.78	0.78, 0.14	6.51, 0.83
	MEDIAN	134.6	160.8	144.2	6.0	6.0	6.0
	MIN, MAX	6.0, 290.8	28.2, 485.1	6.0, 485.1	6.0, 42.4	6.0, 10.5	6.0, 42.4
	5%, 95%	6.0, 290.8	45.6, 411.9	28.2, 405.1	6.0, 40.7	6.0, 6.0	6.0, 10.5
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.0	6.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	140.8, 100.1	140.8, 100.1	6.0, 6.0	NA, NA	6.0, 6.0
	SD, SE	NA, NA	144.69, 83.54	144.69, 83.54	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	62.5	62.5	6.0	NA	6.0
	MIN, MAX	NA, NA	52.2, 307.8	52.2, 307.8	6.0, 6.0	NA, NA	6.0, 6.0
	5%, 95%	NA, NA	52.2, 307.8	52.2, 307.8	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537861

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pg/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	265.2, 265.2	265.2, 265.2	6.0, 6.0	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	265.2	265.2	6.0	6.0	6.0
	MIN, MAX	NA, NA	265.2, 265.2	265.2, 265.2	6.0, 6.0	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	122.7, 92.8	170.1, 136.1	151.6, 117.2	7.7, 7.0	6.2, 6.2	6.9, 6.5
	SD, SE	68.42, 16.13	111.41, 21.05	98.81, 14.57	4.84, 0.91	0.61, 0.11	3.36, 0.43
	MEDIAN	135.9	152.1	138.9	6.0	6.0	6.0
	MIN, MAX	6.0, 233.8	17.1, 474.5	6.0, 474.5	6.0, 24.2	6.0, 8.3	6.0, 24.2
	5%, 95%	6.0, 233.8	28.5, 444.8	20.9, 351.6	6.0, 23.4	6.0, 7.8	6.0, 11.4
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.0	6.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.0, 6.0	6.0, 6.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	149.4, 104.5	149.4, 104.5	6.0, 6.0	NA, NA	6.0, 6.0
	SD, SE	NA, NA	155.01, 89.49	155.01, 89.49	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	72.0	72.0	6.0	NA	6.0
	MIN, MAX	NA, NA	48.4, 327.9	48.4, 327.9	6.0, 6.0	NA, NA	6.0, 6.0
	5%, 95%	NA, NA	48.4, 327.9	48.4, 327.9	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537862

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1194.5, 1194.5	1194.5, 1194.5	28.7, 28.7	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1194.5	1194.5	28.7	28.7	28.7
	MIN, MAX	NA, NA	1194.5, 1194.5	1194.5, 1194.5	28.7, 28.7	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	581.6, 405.8	783.3, 572.6	704.3, 500.4	31.1, 30.0	30.1, 29.8	30.6, 29.9
	SD, SE	399.78, 94.23	550.97, 104.12	502.41, 74.08	12.91, 2.44	4.57, 0.80	9.29, 1.19
	MEDIAN	609.5	720.6	652.0	28.7	28.7	28.7
	MIN, MAX	28.7, 1591.7	28.7, 2315.9	28.7, 2315.9	28.7, 97.0	28.7, 45.9	28.7, 97.0
	5%, 95%	28.7, 1591.7	54.5, 2217.4	54.5, 1591.7	28.7, 28.7	28.7, 45.9	28.7, 40.6
	BLQ Values Included	1	1	2	27	30	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.7	28.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	754.9, 492.1	754.9, 492.1	28.7, 28.7	NA, NA	28.7, 28.7
	SD, SE	NA, NA	798.32, 460.91	798.32, 460.91	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	438.3	438.3	28.7	NA	28.7
	MIN, MAX	NA, NA	163.5, 1663.0	163.5, 1663.0	28.7, 28.7	NA, NA	28.7, 28.7
	5%, 95%	NA, NA	163.5, 1663.0	163.5, 1663.0	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Free NNAL (pmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1340.3, 1340.3	1340.3, 1340.3	28.7, 28.7	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1340.3	1340.3	28.7	28.7	28.7
	MIN, MAX	NA, NA	1340.3, 1340.3	1340.3, 1340.3	28.7, 28.7	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	586.3, 426.0	884.6, 731.2	763.9, 587.6	42.7, 34.2	29.4, 29.2	35.5, 31.4
	SD, SE	388.07, 94.12	563.66, 112.73	516.44, 79.69	45.10, 8.52	3.74, 0.65	31.10, 3.98
	MEDIAN	643.4	768.6	689.0	28.7	28.7	28.7
	MIN, MAX	28.7, 1390.0	134.8, 2318.8	28.7, 2318.8	28.7, 202.7	28.7, 50.2	28.7, 202.7
	5%, 95%	28.7, 1390.0	218.0, 1968.9	134.8, 1936.4	28.7, 194.5	28.7, 28.7	28.7, 50.2
	BLQ Values Included	1	0	1	25	32	57
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.7	28.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	673.2, 478.7	673.2, 478.7	28.7, 28.7	NA, NA	28.7, 28.7
	SD, SE	NA, NA	691.61, 399.30	691.61, 399.30	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	298.8	298.8	28.7	NA	28.7
	MIN, MAX	NA, NA	249.5, 1471.3	249.5, 1471.3	28.7, 28.7	NA, NA	28.7, 28.7
	5%, 95%	NA, NA	249.5, 1471.3	249.5, 1471.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Free NNAL (pmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1267.4, 1267.4	1267.4, 1267.4	28.7, 28.7	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1267.4	1267.4	28.7	28.7	28.7
	MIN, MAX	NA, NA	1267.4, 1267.4	1267.4, 1267.4	28.7, 28.7	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	586.6, 443.3	813.1, 650.6	724.5, 559.9	36.9, 33.3	29.7, 29.6	33.0, 31.3
	SD, SE	327.02, 77.08	532.56, 100.65	472.30, 69.64	23.08, 4.36	2.88, 0.50	16.03, 2.05
	MEDIAN	649.5	726.7	663.9	28.7	28.7	28.7
	MIN, MAX	28.7, 1117.6	81.8, 2268.1	28.7, 2268.1	28.7, 115.7	28.7, 39.5	28.7, 115.7
	5%, 95%	28.7, 1117.6	136.3, 2126.2	99.9, 1680.7	28.7, 111.6	28.7, 37.3	28.7, 54.3
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.7	28.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.7, 28.7	28.7, 28.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	714.1, 499.5	714.1, 499.5	28.7, 28.7	NA, NA	28.7, 28.7
	SD, SE	NA, NA	740.95, 427.79	740.95, 427.79	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	343.9	343.9	28.7	NA	28.7
	MIN, MAX	NA, NA	231.2, 1567.2	231.2, 1567.2	28.7, 28.7	NA, NA	28.7, 28.7
	5%, 95%	NA, NA	231.2, 1567.2	231.2, 1567.2	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2158.8, 2158.8	2158.8, 2158.8	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	2158.8	2158.8	1.0	1.0	1.0
	MIN, MAX	NA, NA	2158.8, 2158.8	2158.8, 2158.8	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1588.4, 986.2	1696.2, 916.9	1654.0, 943.5	4.0, 2.0	1.2, 1.1	2.5, 1.5
	SD, SE	1414.79, 333.47	1884.90, 356.21	1700.21, 250.68	6.52, 1.23	0.80, 0.14	4.64, 0.59
	MEDIAN	1284.7	850.1	1000.4	1.2	1.0	1.0
	MIN, MAX	15.7, 5625.0	42.3, 8096.4	15.7, 8096.4	1.0, 23.2	1.0, 5.4	1.0, 23.2
	5%, 95%	15.7, 5625.0	153.9, 5070.3	153.9, 5070.3	1.0, 22.6	1.0, 2.1	1.0, 8.8
	BLQ Values Included	0	0	0	13	26	39
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.0	1.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	795.4, 441.5	795.4, 441.5	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	849.45, 490.43	849.45, 490.43	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	560.1	560.1	1.0	NA	1.0
	MIN, MAX	NA, NA	88.4, 1737.7	88.4, 1737.7	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	88.4, 1737.7	88.4, 1737.7	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2238.2, 2238.2	2238.2, 2238.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	2238.2	2238.2	1.0	1.0	1.0
	MIN, MAX	NA, NA	2238.2, 2238.2	2238.2, 2238.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1772.2, 1162.4	1844.0, 1124.7	1815.3, 1139.6	6.2, 1.7	1.2, 1.1	3.5, 1.4
	SD, SE	1309.83, 308.73	2212.85, 425.86	1886.17, 281.17	22.81, 4.31	0.59, 0.10	15.52, 1.99
	MEDIAN	1350.6	1096.3	1304.2	1.0	1.0	1.0
	MIN, MAX	11.9, 5120.6	151.2, 10733.1	11.9, 10733.1	1.0, 122.3	1.0, 3.6	1.0, 122.3
	5%, 95%	11.9, 5120.6	192.0, 6116.5	192.0, 5120.6	1.0, 6.8	1.0, 2.8	1.0, 5.1
	BLQ Values Included	0	0	0	17	30	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.2, 1.2	1.2, 1.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.2	1.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.2, 1.2	1.2, 1.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1338.4, 473.2	1338.4, 473.2	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1985.81, 1146.51	1985.81, 1146.51	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	283.0	283.0	1.0	NA	1.0
	MIN, MAX	NA, NA	103.2, 3629.1	103.2, 3629.1	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	103.2, 3629.1	103.2, 3629.1	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537867

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3661.6, 3661.6	3661.6, 3661.6	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	3661.6	3661.6	1.0	1.0	1.0
	MIN, MAX	NA, NA	3661.6, 3661.6	3661.6, 3661.6	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1439.8, 874.6	1718.8, 1225.1	1605.9, 1068.9	2.0, 1.4	1.0, 1.0	1.5, 1.2
	SD, SE	1095.85, 265.78	1310.21, 262.04	1221.76, 188.52	2.78, 0.52	0.20, 0.03	1.93, 0.25
	MEDIAN	939.3	1317.5	1301.9	1.0	1.0	1.0
	MIN, MAX	9.6, 3515.6	51.2, 4831.6	9.6, 4831.6	1.0, 15.2	1.0, 2.1	1.0, 15.2
	5%, 95%	9.6, 3515.6	447.3, 4652.5	253.9, 3911.0	1.0, 5.9	1.0, 1.3	1.0, 2.1
	BLQ Values Included	0	0	0	17	31	48
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.4, 1.4	1.4, 1.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.4	1.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.4, 1.4	1.4, 1.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1001.2, 708.6	1001.2, 708.6	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1004.87, 580.16	1004.87, 580.16	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	551.1	551.1	1.0	NA	1.0
	MIN, MAX	NA, NA	300.0, 2152.4	300.0, 2152.4	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	300.0, 2152.4	300.0, 2152.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537868

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2686.2, 2686.2	2686.2, 2686.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	2686.2	2686.2	1.0	1.0	1.0
	MIN, MAX	NA, NA	2686.2, 2686.2	2686.2, 2686.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1619.5, 1090.0	1691.8, 1070.4	1663.5, 1078.1	4.1, 1.9	1.1, 1.1	2.5, 1.4
	SD, SE	1100.15, 259.31	1688.09, 319.02	1472.52, 217.11	9.15, 1.73	0.42, 0.07	6.32, 0.81
	MEDIAN	1178.2	1264.1	1216.9	1.2	1.0	1.0
	MIN, MAX	12.4, 3783.9	81.6, 7887.0	12.4, 7887.0	1.0, 48.6	1.0, 3.0	1.0, 48.6
	5%, 95%	12.4, 3783.9	218.7, 4037.2	218.7, 3865.6	1.0, 13.0	1.0, 2.0	1.0, 4.5
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.2, 1.2	1.2, 1.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.2	1.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.2, 1.2	1.2, 1.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1045.0, 575.8	1045.0, 575.8	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1274.51, 735.84	1274.51, 735.84	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	464.7	464.7	1.0	NA	1.0
	MIN, MAX	NA, NA	163.9, 2506.4	163.9, 2506.4	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	163.9, 2506.4	163.9, 2506.4	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537869

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13309.0, 13309.0	13309.0, 13309.0	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	13309.0	13309.0	6.2	6.2	6.2
	MIN, MAX	NA, NA	13309.0, 13309.0	13309.0, 13309.0	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	9792.4, 6080.2	10457.2, 5652.9	10197.0, 5816.4	24.9, 12.4	7.6, 7.0	15.5, 9.1
	SD, SE	8722.19, 2055.84	11620.40, 2196.05	10481.80, 1545.45	40.20, 7.60	4.90, 0.85	28.57, 3.66
	MEDIAN	7919.9	5240.6	6167.2	7.4	6.2	6.2
	MIN, MAX	96.8, 34678.1	260.8, 49914.3	96.8, 49914.3	6.2, 143.0	6.2, 33.3	6.2, 143.0
	5%, 95%	96.8, 34678.1	948.8, 31258.4	948.8, 31258.4	6.2, 139.3	6.2, 12.9	6.2, 54.3
	BLQ Values Included	0	0	0	13	26	39
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.2	6.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4903.6, 2721.7	4903.6, 2721.7	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	5236.87, 3023.51	5236.87, 3023.51	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3453.0	3453.0	6.2	NA	6.2
	MIN, MAX	NA, NA	545.0, 10712.9	545.0, 10712.9	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	545.0, 10712.9	545.0, 10712.9	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Nicotine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13798.5, 13798.5	13798.5, 13798.5	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	13798.5	13798.5	6.2	6.2	6.2
	MIN, MAX	NA, NA	13798.5, 13798.5	13798.5, 13798.5	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	10925.7, 7166.2	11368.6, 6933.7	11191.4, 7025.8	38.3, 10.7	7.3, 6.8	21.5, 8.4
	SD, SE	8075.10, 1903.32	13642.20, 2625.45	11628.20, 1733.44	140.65, 26.58	3.64, 0.63	95.66, 12.25
	MEDIAN	8326.5	6758.7	8040.4	6.2	6.2	6.2
	MIN, MAX	73.4, 31568.5	932.1, 66169.6	73.4, 66169.6	6.2, 754.0	6.2, 22.2	6.2, 754.0
	5%, 95%	73.4, 31568.5	1183.7, 37708.2	1183.7, 31568.5	6.2, 41.9	6.2, 17.3	6.2, 31.4
	BLQ Values Included	0	0	0	17	30	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	7.4, 7.4	7.4, 7.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	7.4	7.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	7.4, 7.4	7.4, 7.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	8251.4, 2917.5	8251.4, 2917.5	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	12242.50, 7068.23	12242.50, 7068.23	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1744.7	1744.7	6.2	NA	6.2
	MIN, MAX	NA, NA	636.2, 22373.4	636.2, 22373.4	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	636.2, 22373.4	636.2, 22373.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total Nicotine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	22573.8, 22573.8	22573.8, 22573.8	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	22573.8	22573.8	6.2	6.2	6.2
	MIN, MAX	NA, NA	22573.8, 22573.8	22573.8, 22573.8	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	8876.6, 5391.8	10596.3, 7553.0	9900.2, 6589.7	12.2, 8.9	6.5, 6.4	9.1, 7.4
	SD, SE	6755.88, 1638.54	8077.43, 1615.49	7532.17, 1162.24	17.12, 3.23	1.20, 0.21	11.88, 1.52
	MEDIAN	5790.8	8122.4	8025.9	6.2	6.2	6.2
	MIN, MAX	59.2, 21673.7	315.6, 29786.8	59.2, 29786.8	6.2, 93.7	6.2, 12.9	6.2, 93.7
	5%, 95%	59.2, 21673.7	2757.6, 28682.7	1565.3, 24111.3	6.2, 36.4	6.2, 8.0	6.2, 12.9
	BLQ Values Included	0	0	0	17	31	48
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8.6, 8.6	8.6, 8.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8.6	8.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8.6, 8.6	8.6, 8.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6172.2, 4368.7	6172.2, 4368.7	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	6195.01, 3576.69	6195.01, 3576.69	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3397.5	3397.5	6.2	NA	6.2
	MIN, MAX	NA, NA	1849.5, 13269.5	1849.5, 13269.5	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	1849.5, 13269.5	1849.5, 13269.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537872

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total Nicotine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	16560.4, 16560.4	16560.4, 16560.4	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	16560.4	16560.4	6.2	6.2	6.2
	MIN, MAX	NA, NA	16560.4, 16560.4	16560.4, 16560.4	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	9984.2, 6720.3	10430.0, 6599.2	10255.6, 6646.3	25.1, 11.9	7.1, 6.8	15.4, 8.8
	SD, SE	6782.43, 1598.63	10407.10, 1966.76	9078.09, 1338.49	56.43, 10.66	2.55, 0.44	38.97, 4.99
	MEDIAN	7263.5	7793.0	7502.2	7.2	6.2	6.2
	MIN, MAX	76.5, 23327.7	502.8, 48623.6	76.5, 48623.6	6.2, 299.8	6.2, 18.3	6.2, 299.8
	5%, 95%	76.5, 23327.7	1348.3, 24889.6	1348.3, 23831.4	6.2, 79.9	6.2, 12.5	6.2, 28.0
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	7.4, 7.4	7.4, 7.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	7.4	7.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	7.4, 7.4	7.4, 7.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6442.4, 3549.6	6442.4, 3549.6	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	7857.38, 4536.46	7857.38, 4536.46	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2865.1	2865.1	6.2	NA	6.2
	MIN, MAX	NA, NA	1010.2, 15451.9	1010.2, 15451.9	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	1010.2, 15451.9	1010.2, 15451.9	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537873

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3450.6, 3450.6	3450.6, 3450.6	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	3450.6	3450.6	1.0	1.0	1.0
	MIN, MAX	NA, NA	3450.6, 3450.6	3450.6, 3450.6	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3253.1, 1925.2	3168.4, 2081.0	3201.5, 2018.6	4.7, 2.4	1.7, 1.4	3.1, 1.8
	SD, SE	3277.32, 772.47	2763.27, 522.21	2939.52, 433.41	7.26, 1.37	1.64, 0.29	5.23, 0.67
	MEDIAN	1979.1	2234.6	2020.8	1.8	1.0	1.0
	MIN, MAX	31.6, 12250.5	36.4, 12610.5	31.6, 12610.5	1.0, 35.5	1.0, 7.1	1.0, 35.5
	5%, 95%	31.6, 12250.5	480.7, 8279.7	480.7, 10113.6	1.0, 16.7	1.0, 6.7	1.0, 10.7
	BLQ Values Included	0	0	0	10	21	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.3, 6.3	6.3, 6.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.3	6.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.3, 6.3	6.3, 6.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2879.6, 1472.1	2879.6, 1472.1	1.3, 1.3	NA, NA	1.3, 1.3
	SD, SE	NA, NA	3583.02, 2068.66	3583.02, 2068.66	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1310.7	1310.7	1.3	NA	1.3
	MIN, MAX	NA, NA	348.7, 6979.5	348.7, 6979.5	1.3, 1.3	NA, NA	1.3, 1.3
	5%, 95%	NA, NA	348.7, 6979.5	348.7, 6979.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537874

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3572.4, 3572.4	3572.4, 3572.4	1.0, 1.0	1.2, 1.2	1.1, 1.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.28, 0.20	0.23, 0.13
	MEDIAN	NA	3572.4	3572.4	1.0	1.2	1.0
	MIN, MAX	NA, NA	3572.4, 3572.4	3572.4, 3572.4	1.0, 1.0	1.0, 1.4	1.0, 1.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.4	1.0, 1.4
	BLQ Values Included	NA	0	0	1	1	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	3373.5, 2173.6	3867.2, 2600.6	3669.7, 2420.5	5.5, 2.6	1.8, 1.5	3.5, 1.9
	SD, SE	2964.30, 698.69	3727.42, 717.34	3415.37, 509.13	8.13, 1.54	1.43, 0.25	5.85, 0.75
	MEDIAN	2387.9	2731.6	2690.9	1.6	1.0	1.2
	MIN, MAX	28.5, 13012.2	132.0, 18373.7	28.5, 18373.7	1.0, 33.4	1.0, 5.8	1.0, 33.4
	5%, 95%	28.5, 13012.2	578.7, 9222.8	578.7, 9222.8	1.0, 23.2	1.0, 5.5	1.0, 14.1
	BLQ Values Included	0	0	0	10	20	30
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	5.5, 5.5	5.5, 5.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	5.5	5.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	5.5, 5.5	5.5, 5.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3294.2, 1493.3	3294.2, 1493.3	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	4606.63, 2659.64	4606.63, 2659.64	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	767.4	767.4	1.0	NA	1.0
	MIN, MAX	NA, NA	503.9, 8611.3	503.9, 8611.3	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	503.9, 8611.3	503.9, 8611.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537875

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3560.3, 3560.3	3560.3, 3560.3	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	3560.3	3560.3	1.0	1.0	1.0
	MIN, MAX	NA, NA	3560.3, 3560.3	3560.3, 3560.3	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	2794.4, 1791.9	3259.7, 2515.6	3071.3, 2192.8	3.8, 2.2	1.4, 1.2	2.5, 1.6
	SD, SE	1879.15, 455.76	2169.64, 433.93	2046.21, 315.74	6.36, 1.20	0.88, 0.15	4.49, 0.57
	MEDIAN	2377.4	2429.1	2403.3	1.6	1.0	1.0
	MIN, MAX	20.4, 5701.3	279.8, 7919.1	20.4, 7919.1	1.0, 33.8	1.0, 4.5	1.0, 33.8
	5%, 95%	20.4, 5701.3	726.9, 7304.4	390.5, 6761.2	1.0, 11.7	1.0, 3.8	1.0, 6.1
	BLQ Values Included	0	0	0	12	24	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	8.8, 8.8	8.8, 8.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	8.8	8.8
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	8.8, 8.8	8.8, 8.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2684.4, 1485.1	2684.4, 1485.1	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	3390.60, 1957.57	3390.60, 1957.57	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	919.6	919.6	1.0	NA	1.0
	MIN, MAX	NA, NA	540.2, 6593.4	540.2, 6593.4	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	540.2, 6593.4	540.2, 6593.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537876

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 297 of ?)

Lab: Harrogate
Biomarker: Total Cotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3527.8, 3527.8	3527.8, 3527.8	1.0, 1.0	1.1, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.07, 0.05	0.06, 0.03
	MEDIAN	NA	3527.8	3527.8	1.0	1.1	1.0
	MIN, MAX	NA, NA	3527.8, 3527.8	3527.8, 3527.8	1.0, 1.0	1.0, 1.1	1.0, 1.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.1	1.0, 1.1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3167.0, 2117.4	3336.6, 2396.5	3270.2, 2283.2	4.7, 2.6	1.6, 1.4	3.0, 1.9
	SD, SE	2358.10, 555.81	2683.61, 507.16	2535.50, 373.84	6.03, 1.14	1.10, 0.19	4.40, 0.56
	MEDIAN	3091.3	2198.6	2699.1	2.0	1.0	1.3
	MIN, MAX	26.8, 9891.3	149.4, 12581.8	26.8, 12581.8	1.0, 27.1	1.0, 5.5	1.0, 27.1
	5%, 95%	26.8, 9891.3	672.8, 6386.6	661.4, 7069.9	1.0, 17.1	1.0, 4.1	1.0, 11.3
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.9, 6.9	6.9, 6.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.9	6.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.9, 6.9	6.9, 6.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2952.7, 1508.2	2952.7, 1508.2	1.1, 1.1	NA, NA	1.1, 1.1
	SD, SE	NA, NA	3856.14, 2226.34	3856.14, 2226.34	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	999.2	999.2	1.1	NA	1.1
	MIN, MAX	NA, NA	464.3, 7394.7	464.3, 7394.7	1.1, 1.1	NA, NA	1.1, 1.1
	5%, 95%	NA, NA	464.3, 7394.7	464.3, 7394.7	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537877

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 298 of ?)

Lab: Harrogate
Biomarker: Total Cotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	19582.2, 19582.2	19582.2, 19582.2	5.7, 5.7	5.7, 5.7	5.7, 5.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	19582.2	19582.2	5.7	5.7	5.7
	MIN, MAX	NA, NA	19582.2, 19582.2	19582.2, 19582.2	5.7, 5.7	5.7, 5.7	5.7, 5.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 5.7	5.7, 5.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	18461.1, 10925.4	17980.5, 11809.6	18168.6, 11455.4	26.6, 13.7	9.8, 7.8	17.5, 10.1
	SD, SE	18598.80, 4383.78	15681.60, 2963.53	16681.80, 2459.59	41.21, 7.79	9.29, 1.62	29.70, 3.80
	MEDIAN	11231.4	12681.1	11468.1	10.0	5.7	5.7
	MIN, MAX	179.3, 69521.6	206.6, 71564.6	179.3, 71564.6	5.7, 201.5	5.7, 40.3	5.7, 201.5
	5%, 95%	179.3, 69521.6	2728.0, 46987.3	2728.0, 57394.7	5.7, 94.8	5.7, 38.0	5.7, 60.7
	BLQ Values Included	0	0	0	10	21	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	35.8, 35.8	35.8, 35.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	35.8	35.8
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	35.8, 35.8	35.8, 35.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	16341.9, 8354.0	16341.9, 8354.0	7.4, 7.4	NA, NA	7.4, 7.4
	SD, SE	NA, NA	20333.70, 11739.60	20333.70, 11739.60	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7438.2	7438.2	7.4	NA	7.4
	MIN, MAX	NA, NA	1978.9, 39608.7	1978.9, 39608.7	7.4, 7.4	NA, NA	7.4, 7.4
	5%, 95%	NA, NA	1978.9, 39608.7	1978.9, 39608.7	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total Cotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	20273.4, 20273.4	20273.4, 20273.4	5.7, 5.7	6.8, 6.7	6.4, 6.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.56, 1.10	1.27, 0.73
	MEDIAN	NA	20273.4	20273.4	5.7	6.8	5.7
	MIN, MAX	NA, NA	20273.4, 20273.4	20273.4, 20273.4	5.7, 5.7	5.7, 7.9	5.7, 7.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 7.9	5.7, 7.9
	BLQ Values Included	NA	0	0	1	1	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	19144.4, 12334.9	21946.5, 14758.1	20825.6, 13736.4	31.2, 14.7	10.3, 8.4	19.9, 10.8
	SD, SE	16822.40, 3965.07	21153.10, 4070.92	19382.20, 2889.33	46.14, 8.72	8.10, 1.41	33.22, 4.25
	MEDIAN	13551.4	15501.8	15270.9	8.8	5.7	6.8
	MIN, MAX	161.7, 73844.2	749.1, 104270.7	161.7, 104270.7	5.7, 189.5	5.7, 32.9	5.7, 189.5
	5%, 95%	161.7, 73844.2	3284.1, 52339.4	3284.1, 52339.4	5.7, 131.7	5.7, 31.2	5.7, 80.0
	BLQ Values Included	0	0	0	10	20	30
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	31.2, 31.2	31.2, 31.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	31.2	31.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	31.2, 31.2	31.2, 31.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	18694.6, 8474.4	18694.6, 8474.4	5.7, 5.7	NA, NA	5.7, 5.7
	SD, SE	NA, NA	26142.60, 15093.40	26142.60, 15093.40	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	4355.0	4355.0	5.7	NA	5.7
	MIN, MAX	NA, NA	2859.6, 48869.1	2859.6, 48869.1	5.7, 5.7	NA, NA	5.7, 5.7
	5%, 95%	NA, NA	2859.6, 48869.1	2859.6, 48869.1	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537879

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 300 of ?)

Lab: Harrogate
Biomarker: Total Cotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	20204.7, 20204.7	20204.7, 20204.7	5.7, 5.7	5.7, 5.7	5.7, 5.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	20204.7	20204.7	5.7	5.7	5.7
	MIN, MAX	NA, NA	20204.7, 20204.7	20204.7, 20204.7	5.7, 5.7	5.7, 5.7	5.7, 5.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 5.7	5.7, 5.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	15858.2, 10169.2	18498.7, 14275.8	17429.9, 12444.4	21.6, 12.5	7.7, 6.9	14.1, 9.0
	SD, SE	10664.20, 2586.44	12312.70, 2462.54	11612.20, 1791.81	36.10, 6.82	4.98, 0.87	25.47, 3.26
	MEDIAN	13491.7	13785.1	13638.4	9.1	5.7	5.7
	MIN, MAX	115.8, 32354.9	1587.9, 44940.9	115.8, 44940.9	5.7, 191.8	5.7, 25.5	5.7, 191.8
	5%, 95%	115.8, 32354.9	4125.2, 41452.5	2216.1, 38369.8	5.7, 66.4	5.7, 21.6	5.7, 34.6
	BLQ Values Included	0	0	0	12	24	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	49.9, 49.9	49.9, 49.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	49.9	49.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	49.9, 49.9	49.9, 49.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	15233.9, 8427.9	15233.9, 8427.9	5.7, 5.7	NA, NA	5.7, 5.7
	SD, SE	NA, NA	19241.70, 11109.20	19241.70, 11109.20	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5218.7	5218.7	5.7	NA	5.7
	MIN, MAX	NA, NA	3065.6, 37417.5	3065.6, 37417.5	5.7, 5.7	NA, NA	5.7, 5.7
	5%, 95%	NA, NA	3065.6, 37417.5	3065.6, 37417.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537880

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 301 of ?)

Lab: Harrogate
Biomarker: Total Cotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	20020.1, 20020.1	20020.1, 20020.1	5.7, 5.7	6.1, 6.0	5.9, 5.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.49, 0.35	0.40, 0.23
	MEDIAN	NA	20020.1	20020.1	5.7	6.1	5.7
	MIN, MAX	NA, NA	20020.1, 20020.1	20020.1, 20020.1	5.7, 5.7	5.7, 6.4	5.7, 6.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 6.4	5.7, 6.4
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	17972.4, 12017.3	18935.4, 13600.2	18558.5, 12957.4	26.5, 15.1	9.3, 8.0	17.2, 10.7
	SD, SE	13382.20, 3154.22	15229.60, 2878.11	14389.00, 2121.54	34.17, 6.46	6.24, 1.09	24.92, 3.19
	MEDIAN	17543.0	12476.8	15317.2	11.6	5.7	7.4
	MIN, MAX	152.3, 56133.3	847.9, 71401.7	152.3, 71401.7	5.7, 153.6	5.7, 31.0	5.7, 153.6
	5%, 95%	152.3, 56133.3	3818.0, 36244.1	3753.3, 40121.5	5.7, 97.2	5.7, 23.3	5.7, 64.0
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	39.0, 39.0	39.0, 39.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	39.0	39.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	39.0, 39.0	39.0, 39.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	16756.8, 8558.9	16756.8, 8558.9	6.3, 6.3	NA, NA	6.3, 6.3
	SD, SE	NA, NA	21883.70, 12634.60	21883.70, 12634.60	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5670.6	5670.6	6.3	NA	6.3
	MIN, MAX	NA, NA	2634.7, 41965.1	2634.7, 41965.1	6.3, 6.3	NA, NA	6.3, 6.3
	5%, 95%	NA, NA	2634.7, 41965.1	2634.7, 41965.1	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537881

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1974.4, 1974.4	1974.4, 1974.4	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1974.4	1974.4	1.0	1.0	1.0
	MIN, MAX	NA, NA	1974.4, 1974.4	1974.4, 1974.4	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1071.6, 695.2	1223.2, 600.6	1163.9, 636.0	3.6, 1.7	1.2, 1.1	2.3, 1.3
	SD, SE	894.09, 210.74	1436.66, 271.50	1243.37, 183.33	6.18, 1.17	1.01, 0.18	4.38, 0.56
	MEDIAN	810.1	597.3	649.3	1.0	1.0	1.0
	MIN, MAX	12.8, 3752.0	32.7, 6329.6	12.8, 6329.6	1.0, 24.5	1.0, 6.8	1.0, 24.5
	5%, 95%	12.8, 3752.0	45.8, 3781.9	45.8, 3752.0	1.0, 20.9	1.0, 1.2	1.0, 6.8
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.0	1.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	525.7, 337.9	525.7, 337.9	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	459.98, 265.57	459.98, 265.57	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	504.2	504.2	1.0	NA	1.0
	MIN, MAX	NA, NA	76.8, 996.0	76.8, 996.0	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	76.8, 996.0	76.8, 996.0	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1484.2, 1484.2	1484.2, 1484.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1484.2	1484.2	1.0	1.0	1.0
	MIN, MAX	NA, NA	1484.2, 1484.2	1484.2, 1484.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1278.9, 872.3	1267.9, 732.7	1272.3, 785.6	5.3, 1.5	1.1, 1.1	3.1, 1.3
	SD, SE	900.59, 212.27	1498.92, 288.47	1281.02, 190.96	19.81, 3.74	0.60, 0.10	13.46, 1.72
	MEDIAN	993.7	730.7	835.4	1.0	1.0	1.0
	MIN, MAX	12.2, 3489.6	67.2, 6634.3	12.2, 6634.3	1.0, 106.2	1.0, 4.3	1.0, 106.2
	5%, 95%	12.2, 3489.6	92.9, 4961.8	92.9, 3489.6	1.0, 5.7	1.0, 2.1	1.0, 4.3
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.0	1.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	764.4, 342.2	764.4, 342.2	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1043.34, 602.37	1043.34, 602.37	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	244.2	244.2	1.0	NA	1.0
	MIN, MAX	NA, NA	83.5, 1965.6	83.5, 1965.6	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	83.5, 1965.6	83.5, 1965.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 304 of ?)

Lab: Harrogate
Biomarker: Free Nicotine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2851.0, 2851.0	2851.0, 2851.0	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	2851.0	2851.0	1.0	1.0	1.0
	MIN, MAX	NA, NA	2851.0, 2851.0	2851.0, 2851.0	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1075.5, 596.6	1218.8, 839.4	1160.8, 731.1	1.5, 1.2	1.0, 1.0	1.3, 1.1
	SD, SE	898.87, 218.01	958.30, 191.66	926.25, 142.92	1.86, 0.35	0.07, 0.01	1.27, 0.16
	MEDIAN	820.2	1123.3	911.3	1.0	1.0	1.0
	MIN, MAX	5.2, 3006.4	30.0, 3630.2	5.2, 3630.2	1.0, 10.5	1.0, 1.4	1.0, 10.5
	5%, 95%	5.2, 3006.4	291.1, 3563.7	131.0, 3006.4	1.0, 4.0	1.0, 1.0	1.0, 1.7
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.0	1.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	687.5, 570.2	687.5, 570.2	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	519.68, 300.04	519.68, 300.04	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	487.0	487.0	1.0	NA	1.0
	MIN, MAX	NA, NA	298.0, 1277.6	298.0, 1277.6	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	298.0, 1277.6	298.0, 1277.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 305 of ?)

Lab: Harrogate
Biomarker: Free Nicotine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2103.2, 2103.2	2103.2, 2103.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	2103.2	2103.2	1.0	1.0	1.0
	MIN, MAX	NA, NA	2103.2, 2103.2	2103.2, 2103.2	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1160.2, 803.0	1192.8, 722.7	1180.0, 753.1	3.5, 1.7	1.1, 1.1	2.2, 1.3
	SD, SE	733.75, 172.95	1202.54, 227.26	1035.04, 152.61	8.00, 1.51	0.44, 0.08	5.51, 0.71
	MEDIAN	947.1	705.4	815.5	1.1	1.0	1.0
	MIN, MAX	10.1, 2449.9	65.6, 5531.4	10.1, 5531.4	1.0, 42.7	1.0, 3.3	1.0, 42.7
	5%, 95%	10.1, 2449.9	69.4, 3012.0	69.4, 2950.7	1.0, 9.9	1.0, 2.1	1.0, 3.3
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.0	1.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	659.2, 446.3	659.2, 446.3	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	665.59, 384.28	665.59, 384.28	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	411.8	411.8	1.0	NA	1.0
	MIN, MAX	NA, NA	152.8, 1413.1	152.8, 1413.1	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	152.8, 1413.1	152.8, 1413.1	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12172.2, 12172.2	12172.2, 12172.2	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	12172.2	12172.2	6.2	6.2	6.2
	MIN, MAX	NA, NA	12172.2, 12172.2	12172.2, 12172.2	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	6606.6, 4285.8	7541.1, 3702.7	7175.4, 3920.8	21.9, 10.7	7.3, 6.6	14.0, 8.2
	SD, SE	5512.07, 1299.21	8856.99, 1673.81	7665.40, 1130.20	38.09, 7.20	6.21, 1.08	26.96, 3.45
	MEDIAN	4994.3	3682.4	4002.7	6.2	6.2	6.2
	MIN, MAX	78.9, 23131.1	201.6, 39022.0	78.9, 39022.0	6.2, 151.0	6.2, 41.9	6.2, 151.0
	5%, 95%	78.9, 23131.1	282.4, 23315.4	282.4, 23131.1	6.2, 128.8	6.2, 7.4	6.2, 41.9
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.2	6.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3240.7, 2083.0	3240.7, 2083.0	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	2835.72, 1637.20	2835.72, 1637.20	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3108.4	3108.4	6.2	NA	6.2
	MIN, MAX	NA, NA	473.5, 6140.3	473.5, 6140.3	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	473.5, 6140.3	473.5, 6140.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537886

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Nicotine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	9150.1, 9150.1	9150.1, 9150.1	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	9150.1	9150.1	6.2	6.2	6.2
	MIN, MAX	NA, NA	9150.1, 9150.1	9150.1, 9150.1	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	7884.4, 5377.8	7816.6, 4516.9	7843.7, 4843.3	33.0, 9.6	7.1, 6.7	19.0, 7.9
	SD, SE	5552.14, 1308.65	9240.82, 1778.40	7897.51, 1177.29	122.12, 23.08	3.68, 0.64	82.99, 10.63
	MEDIAN	6126.2	4504.8	5150.2	6.2	6.2	6.2
	MIN, MAX	75.2, 21513.4	414.3, 40900.5	75.2, 40900.5	6.2, 654.7	6.2, 26.5	6.2, 654.7
	5%, 95%	75.2, 21513.4	572.7, 30589.5	572.7, 21513.4	6.2, 35.1	6.2, 12.9	6.2, 26.5
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.2	6.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4712.7, 2109.8	4712.7, 2109.8	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	6432.16, 3713.61	6432.16, 3713.61	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1505.5	1505.5	6.2	NA	6.2
	MIN, MAX	NA, NA	514.8, 12117.9	514.8, 12117.9	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	514.8, 12117.9	514.8, 12117.9	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537887

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 308 of ?)

Lab: Harrogate
Biomarker: Free Nicotine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17576.4, 17576.4	17576.4, 17576.4	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	17576.4	17576.4	6.2	6.2	6.2
	MIN, MAX	NA, NA	17576.4, 17576.4	17576.4, 17576.4	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	6630.4, 3678.3	7514.0, 5175.1	7156.4, 4507.1	9.5, 7.5	6.3, 6.3	7.7, 6.8
	SD, SE	5541.54, 1344.02	5907.93, 1181.59	5710.34, 881.12	11.44, 2.16	0.42, 0.07	7.85, 1.00
	MEDIAN	5056.5	6925.1	5618.2	6.2	6.2	6.2
	MIN, MAX	32.1, 18534.5	185.0, 22380.2	32.1, 22380.2	6.2, 64.7	6.2, 8.6	6.2, 64.7
	5%, 95%	32.1, 18534.5	1794.6, 21970.2	807.6, 18534.5	6.2, 24.7	6.2, 6.2	6.2, 10.5
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.2	6.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4238.7, 3515.5	4238.7, 3515.5	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	3203.79, 1849.71	3203.79, 1849.71	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3002.4	3002.4	6.2	NA	6.2
	MIN, MAX	NA, NA	1837.2, 7876.4	1837.2, 7876.4	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	1837.2, 7876.4	1837.2, 7876.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Nicotine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12966.2, 12966.2	12966.2, 12966.2	6.2, 6.2	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	12966.2	12966.2	6.2	6.2	6.2
	MIN, MAX	NA, NA	12966.2, 12966.2	12966.2, 12966.2	6.2, 6.2	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	7152.5, 4949.8	7353.5, 4455.5	7274.8, 4642.8	21.4, 10.5	6.9, 6.6	13.6, 8.2
	SD, SE	4523.60, 1066.22	7413.67, 1401.05	6381.05, 940.83	49.32, 9.32	2.69, 0.47	33.94, 4.35
	MEDIAN	5838.7	4348.7	5027.4	6.5	6.2	6.2
	MIN, MAX	62.1, 15103.7	404.2, 34100.9	62.1, 34100.9	6.2, 263.2	6.2, 20.3	6.2, 263.2
	5%, 95%	62.1, 15103.7	427.6, 18569.2	427.6, 18191.3	6.2, 60.8	6.2, 13.0	6.2, 20.3
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.2	6.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.2, 6.2	6.2, 6.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4064.0, 2751.4	4064.0, 2751.4	6.2, 6.2	NA, NA	6.2, 6.2
	SD, SE	NA, NA	4103.27, 2369.02	4103.27, 2369.02	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2538.8	2538.8	6.2	NA	6.2
	MIN, MAX	NA, NA	941.8, 8711.5	941.8, 8711.5	6.2, 6.2	NA, NA	6.2, 6.2
	5%, 95%	NA, NA	941.8, 8711.5	941.8, 8711.5	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1841.9, 1841.9	1841.9, 1841.9	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1841.9	1841.9	1.0	1.0	1.0
	MIN, MAX	NA, NA	1841.9, 1841.9	1841.9, 1841.9	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1001.8, 749.5	1000.2, 760.8	1000.9, 756.4	2.3, 1.6	1.2, 1.1	1.7, 1.3
	SD, SE	574.80, 135.48	585.43, 110.64	574.85, 84.76	3.00, 0.57	0.69, 0.12	2.16, 0.28
	MEDIAN	925.7	911.1	919.4	1.0	1.0	1.0
	MIN, MAX	19.0, 2263.4	18.2, 2534.2	18.2, 2534.2	1.0, 14.1	1.0, 4.8	1.0, 14.1
	5%, 95%	19.0, 2263.4	226.0, 1856.6	226.0, 1953.5	1.0, 10.0	1.0, 2.1	1.0, 4.8
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.2, 2.2	2.2, 2.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.2	2.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.2, 2.2	2.2, 2.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1196.7, 812.4	1196.7, 812.4	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1249.70, 721.51	1249.70, 721.51	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	648.8	648.8	1.0	NA	1.0
	MIN, MAX	NA, NA	314.6, 2626.8	314.6, 2626.8	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	314.6, 2626.8	314.6, 2626.8	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 311 of ?)

Lab: Harrogate
Biomarker: Free Cotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1341.6, 1341.6	1341.6, 1341.6	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1341.6	1341.6	1.0	1.0	1.0
	MIN, MAX	NA, NA	1341.6, 1341.6	1341.6, 1341.6	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	1183.3, 887.6	1126.9, 876.6	1149.5, 881.0	2.8, 1.7	1.1, 1.1	1.9, 1.3
	SD, SE	626.79, 147.74	872.59, 167.93	776.20, 115.71	4.26, 0.81	0.33, 0.06	2.99, 0.38
	MEDIAN	1065.2	975.4	975.4	1.0	1.0	1.0
	MIN, MAX	15.5, 2343.3	81.5, 4778.6	15.5, 4778.6	1.0, 20.8	1.0, 2.4	1.0, 20.8
	5%, 95%	15.5, 2343.3	221.4, 1775.4	221.4, 2191.1	1.0, 11.7	1.0, 2.0	1.0, 4.1
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.5, 2.5	2.5, 2.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.5	2.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.5, 2.5	2.5, 2.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1172.5, 794.3	1172.5, 794.3	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1276.71, 737.11	1276.71, 737.11	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	449.2	449.2	1.0	NA	1.0
	MIN, MAX	NA, NA	421.6, 2646.6	421.6, 2646.6	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	421.6, 2646.6	421.6, 2646.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1210.8, 1210.8	1210.8, 1210.8	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1210.8	1210.8	1.0	1.0	1.0
	MIN, MAX	NA, NA	1210.8, 1210.8	1210.8, 1210.8	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	1107.1, 728.7	1049.7, 906.7	1072.9, 829.9	2.1, 1.4	1.0, 1.0	1.5, 1.2
	SD, SE	744.03, 180.45	503.70, 100.74	604.45, 93.27	3.60, 0.68	0.05, 0.01	2.48, 0.32
	MEDIAN	844.3	1005.9	998.4	1.0	1.0	1.0
	MIN, MAX	6.1, 2858.1	121.1, 2101.4	6.1, 2858.1	1.0, 19.9	1.0, 1.2	1.0, 19.9
	5%, 95%	6.1, 2858.1	311.8, 2045.1	257.2, 2101.4	1.0, 5.3	1.0, 1.2	1.0, 2.6
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	3.7, 3.7	3.7, 3.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	3.7	3.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	3.7, 3.7	3.7, 3.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1179.1, 837.8	1179.1, 837.8	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1213.85, 700.82	1213.85, 700.82	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	512.0	512.0	1.0	NA	1.0
	MIN, MAX	NA, NA	445.1, 2580.2	445.1, 2580.2	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	445.1, 2580.2	445.1, 2580.2	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1464.8, 1464.8	1464.8, 1464.8	1.0, 1.0	1.0, 1.0	1.0, 1.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	1464.8	1464.8	1.0	1.0	1.0
	MIN, MAX	NA, NA	1464.8, 1464.8	1464.8, 1464.8	1.0, 1.0	1.0, 1.0	1.0, 1.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 1.0
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	1101.6, 829.0	1035.6, 844.0	1061.4, 838.1	2.4, 1.7	1.1, 1.1	1.7, 1.3
	SD, SE	549.70, 129.57	613.34, 115.91	583.89, 86.09	3.05, 0.58	0.31, 0.05	2.16, 0.28
	MEDIAN	1065.0	914.3	970.2	1.2	1.0	1.0
	MIN, MAX	13.5, 1962.5	73.6, 3090.2	13.5, 3090.2	1.0, 13.9	1.0, 2.7	1.0, 13.9
	5%, 95%	13.5, 1962.5	275.9, 1778.5	275.9, 1876.0	1.0, 10.6	1.0, 1.4	1.0, 4.1
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.8, 2.8	2.8, 2.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.8	2.8
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.8, 2.8	2.8, 2.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1182.8, 825.5	1182.8, 825.5	1.0, 1.0	NA, NA	1.0, 1.0
	SD, SE	NA, NA	1243.47, 717.92	1243.47, 717.92	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	505.2	505.2	1.0	NA	1.0
	MIN, MAX	NA, NA	425.3, 2617.9	425.3, 2617.9	1.0, 1.0	NA, NA	1.0, 1.0
	5%, 95%	NA, NA	425.3, 2617.9	425.3, 2617.9	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free Cotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10452.8, 10452.8	10452.8, 10452.8	5.7, 5.7	5.7, 5.7	5.7, 5.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	10452.8	10452.8	5.7	5.7	5.7
	MIN, MAX	NA, NA	10452.8, 10452.8	10452.8, 10452.8	5.7, 5.7	5.7, 5.7	5.7, 5.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 5.7	5.7, 5.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5685.4, 4253.4	5676.3, 4317.8	5679.8, 4292.5	13.3, 9.1	6.6, 6.2	9.7, 7.4
	SD, SE	3262.01, 768.86	3322.32, 627.86	3262.29, 481.00	17.01, 3.22	3.87, 0.67	12.23, 1.57
	MEDIAN	5253.1	5170.2	5217.3	5.7	5.7	5.7
	MIN, MAX	107.8, 12844.8	103.3, 14381.6	103.3, 14381.6	5.7, 80.0	5.7, 27.2	5.7, 80.0
	5%, 95%	107.8, 12844.8	1282.6, 10536.2	1282.6, 11086.1	5.7, 56.8	5.7, 11.9	5.7, 27.2
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	12.5, 12.5	12.5, 12.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	12.5	12.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	12.5, 12.5	12.5, 12.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6791.5, 4610.3	6791.5, 4610.3	5.7, 5.7	NA, NA	5.7, 5.7
	SD, SE	NA, NA	7092.02, 4094.58	7092.02, 4094.58	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3681.9	3681.9	5.7	NA	5.7
	MIN, MAX	NA, NA	1785.4, 14907.1	1785.4, 14907.1	5.7, 5.7	NA, NA	5.7, 5.7
	5%, 95%	NA, NA	1785.4, 14907.1	1785.4, 14907.1	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 315 of ?)

Lab: Harrogate
Biomarker: Free Cotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	7613.6, 7613.6	7613.6, 7613.6	5.7, 5.7	5.7, 5.7	5.7, 5.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	7613.6	7613.6	5.7	5.7	5.7
	MIN, MAX	NA, NA	7613.6, 7613.6	7613.6, 7613.6	5.7, 5.7	5.7, 5.7	5.7, 5.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 5.7	5.7, 5.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	6715.1, 5037.2	6395.4, 4974.7	6523.3, 4999.6	16.0, 9.7	6.4, 6.2	10.8, 7.6
	SD, SE	3557.04, 838.40	4951.93, 953.00	4404.96, 656.65	24.19, 4.57	1.86, 0.32	16.98, 2.17
	MEDIAN	6045.1	5535.4	5535.4	5.7	5.7	5.7
	MIN, MAX	88.0, 13298.2	462.5, 27118.6	88.0, 27118.6	5.7, 118.0	5.7, 13.6	5.7, 118.0
	5%, 95%	88.0, 13298.2	1256.4, 10075.4	1256.4, 12434.5	5.7, 66.4	5.7, 11.4	5.7, 23.3
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	14.2, 14.2	14.2, 14.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	14.2	14.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	14.2, 14.2	14.2, 14.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6653.8, 4507.9	6653.8, 4507.9	5.7, 5.7	NA, NA	5.7, 5.7
	SD, SE	NA, NA	7245.36, 4183.11	7245.36, 4183.11	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2549.2	2549.2	5.7	NA	5.7
	MIN, MAX	NA, NA	2392.6, 15019.5	2392.6, 15019.5	5.7, 5.7	NA, NA	5.7, 5.7
	5%, 95%	NA, NA	2392.6, 15019.5	2392.6, 15019.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free Cotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	6871.3, 6871.3	6871.3, 6871.3	5.7, 5.7	5.7, 5.7	5.7, 5.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	6871.3	6871.3	5.7	5.7	5.7
	MIN, MAX	NA, NA	6871.3, 6871.3	6871.3, 6871.3	5.7, 5.7	5.7, 5.7	5.7, 5.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 5.7	5.7, 5.7
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	6282.8, 4135.0	5957.1, 5145.3	6089.0, 4709.6	12.1, 8.2	5.8, 5.8	8.7, 6.8
	SD, SE	4222.34, 1024.07	2858.49, 571.70	3430.24, 529.30	20.44, 3.86	0.27, 0.05	14.08, 1.80
	MEDIAN	4791.4	5708.5	5665.7	5.7	5.7	5.7
	MIN, MAX	34.6, 16219.7	687.2, 11925.4	34.6, 16219.7	5.7, 112.9	5.7, 6.8	5.7, 112.9
	5%, 95%	34.6, 16219.7	1769.5, 11605.9	1459.6, 11925.4	5.7, 30.1	5.7, 6.8	5.7, 14.8
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	21.0, 21.0	21.0, 21.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	21.0	21.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	21.0, 21.0	21.0, 21.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6691.4, 4754.3	6691.4, 4754.3	5.7, 5.7	NA, NA	5.7, 5.7
	SD, SE	NA, NA	6888.59, 3977.13	6888.59, 3977.13	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2905.6	2905.6	5.7	NA	5.7
	MIN, MAX	NA, NA	2525.9, 14642.6	2525.9, 14642.6	5.7, 5.7	NA, NA	5.7, 5.7
	5%, 95%	NA, NA	2525.9, 14642.6	2525.9, 14642.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537896

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 317 of ?)

Lab: Harrogate
Biomarker: Free Cotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	8312.6, 8312.6	8312.6, 8312.6	5.7, 5.7	5.7, 5.7	5.7, 5.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	8312.6	8312.6	5.7	5.7	5.7
	MIN, MAX	NA, NA	8312.6, 8312.6	8312.6, 8312.6	5.7, 5.7	5.7, 5.7	5.7, 5.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.7, 5.7	5.7, 5.7
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	6251.7, 4705.3	5877.1, 4789.4	6023.7, 4756.3	13.8, 9.5	6.3, 6.1	9.7, 7.5
	SD, SE	3119.51, 735.28	3480.75, 657.80	3313.58, 488.56	17.28, 3.27	1.78, 0.31	12.27, 1.57
	MEDIAN	6043.6	5188.9	5505.8	6.5	5.7	5.7
	MIN, MAX	76.8, 11137.0	417.7, 17537.1	76.8, 17537.1	5.7, 78.7	5.7, 15.5	5.7, 78.7
	5%, 95%	76.8, 11137.0	1566.0, 10093.0	1566.0, 10646.3	5.7, 60.2	5.7, 8.1	5.7, 23.5
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	15.9, 15.9	15.9, 15.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	15.9	15.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	15.9, 15.9	15.9, 15.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6712.2, 4684.3	6712.2, 4684.3	5.7, 5.7	NA, NA	5.7, 5.7
	SD, SE	NA, NA	7056.73, 4074.20	7056.73, 4074.20	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2866.8	2866.8	5.7	NA	5.7
	MIN, MAX	NA, NA	2413.4, 14856.4	2413.4, 14856.4	5.7, 5.7	NA, NA	5.7, 5.7
	5%, 95%	NA, NA	2413.4, 14856.4	2413.4, 14856.4	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537897

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2212.4, 2212.4	2212.4, 2212.4	3.1, 3.1	2.1, 1.8	2.4, 2.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.56, 1.10	1.24, 0.72
	MEDIAN	NA	2212.4	2212.4	3.1	2.1	3.1
	MIN, MAX	NA, NA	2212.4, 2212.4	2212.4, 2212.4	3.1, 3.1	1.0, 3.2	1.0, 3.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 3.2	1.0, 3.2
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5422.5, 3090.8	4696.5, 3303.8	4980.6, 3218.8	8.8, 3.6	2.3, 1.6	5.3, 2.3
	SD, SE	6007.04, 1415.87	3494.45, 660.39	4592.06, 677.06	18.07, 3.41	3.10, 0.54	12.75, 1.63
	MEDIAN	3942.6	3971.5	3966.8	2.8	1.0	1.5
	MIN, MAX	57.0, 26581.8	67.5, 15165.6	57.0, 26581.8	1.0, 96.1	1.0, 18.0	1.0, 96.1
	5%, 95%	57.0, 26581.8	602.2, 12291.4	602.2, 12291.4	1.0, 21.5	1.0, 5.9	1.0, 18.0
	BLQ Values Included	0	0	0	8	15	23
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	14.4, 14.4	14.4, 14.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	14.4	14.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	14.4, 14.4	14.4, 14.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3647.3, 2339.6	3647.3, 2339.6	4.9, 4.9	NA, NA	4.9, 4.9
	SD, SE	NA, NA	3288.56, 1898.65	3288.56, 1898.65	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3298.4	3298.4	4.9	NA	4.9
	MIN, MAX	NA, NA	547.1, 7096.4	547.1, 7096.4	4.9, 4.9	NA, NA	4.9, 4.9
	5%, 95%	NA, NA	547.1, 7096.4	547.1, 7096.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 319 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2714.0, 2714.0	2714.0, 2714.0	4.4, 4.4	2.9, 2.2	3.4, 2.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.69, 1.90	2.09, 1.21
	MEDIAN	NA	2714.0	2714.0	4.4	2.9	4.4
	MIN, MAX	NA, NA	2714.0, 2714.0	2714.0, 2714.0	4.4, 4.4	1.0, 4.8	1.0, 4.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 4.8	1.0, 4.8
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	5759.2, 3582.1	6438.5, 4596.8	6166.8, 4160.3	13.9, 4.3	2.8, 1.8	7.9, 2.7
	SD, SE	5203.34, 1226.44	4757.30, 915.54	4893.60, 729.50	32.89, 6.22	3.67, 0.64	22.91, 2.93
	MEDIAN	4781.9	5060.3	4954.9	2.6	1.3	1.9
	MIN, MAX	53.8, 23327.3	276.3, 16335.0	53.8, 23327.3	1.0, 169.4	1.0, 17.5	1.0, 169.4
	5%, 95%	53.8, 23327.3	968.5, 16284.7	807.0, 16284.7	1.0, 57.6	1.0, 13.6	1.0, 26.2
	BLQ Values Included	0	0	0	2	13	15
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10.0, 10.0	10.0, 10.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10.0	10.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10.0, 10.0	10.0, 10.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4240.4, 2628.5	4240.4, 2628.5	2.5, 2.5	NA, NA	2.5, 2.5
	SD, SE	NA, NA	5007.82, 2891.27	5007.82, 2891.27	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1447.2	1447.2	2.5	NA	2.5
	MIN, MAX	NA, NA	1252.1, 10021.8	1252.1, 10021.8	2.5, 2.5	NA, NA	2.5, 2.5
	5%, 95%	NA, NA	1252.1, 10021.8	1252.1, 10021.8	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3320.0, 3320.0	3320.0, 3320.0	2.6, 2.6	1.7, 1.5	2.0, 1.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.99, 0.70	0.87, 0.50
	MEDIAN	NA	3320.0	3320.0	2.6	1.7	2.4
	MIN, MAX	NA, NA	3320.0, 3320.0	3320.0, 3320.0	2.6, 2.6	1.0, 2.4	1.0, 2.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 2.4	1.0, 2.6
	DLQ Values Included	NA	0	0	0	1	1
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	4831.2, 2900.2	5449.3, 4114.2	5199.1, 3571.3	7.2, 3.3	1.9, 1.5	4.3, 2.1
	SD, SE	3990.41, 967.82	4645.96, 929.19	4352.40, 671.59	13.35, 2.52	1.65, 0.29	9.42, 1.21
	MEDIAN	4218.2	4076.6	4147.4	2.6	1.0	1.2
	MIN, MAX	49.9, 14967.4	703.4, 23404.7	49.9, 23404.7	1.0, 69.1	1.0, 6.9	1.0, 69.1
	5%, 95%	49.9, 14967.4	935.8, 11352.7	703.4, 12479.5	1.0, 21.9	1.0, 5.7	1.0, 15.6
	BLQ Values Included	0	0	0	7	18	25
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	12.5, 12.5	12.5, 12.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	12.5	12.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	12.5, 12.5	12.5, 12.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3557.6, 2457.6	3557.6, 2457.6	1.5, 1.5	NA, NA	1.5, 1.5
	SD, SE	NA, NA	3559.40, 2055.02	3559.40, 2055.02	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2172.9	2172.9	1.5	NA	1.5
	MIN, MAX	NA, NA	898.7, 7601.3	898.7, 7601.3	1.5, 1.5	NA, NA	1.5, 1.5
	5%, 95%	NA, NA	898.7, 7601.3	898.7, 7601.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 321 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2748.8, 2748.8	2748.8, 2748.8	3.4, 3.4	2.3, 1.9	2.6, 2.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.77, 1.25	1.42, 0.82
	MEDIAN	NA	2748.8	2748.8	3.4	2.3	3.4
	MIN, MAX	NA, NA	2748.8, 2748.8	2748.8, 2748.8	3.4, 3.4	1.0, 3.5	1.0, 3.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 3.5	1.0, 3.5
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	5401.5, 3535.5	5389.9, 4059.9	5394.5, 3846.1	9.9, 4.3	2.3, 1.8	5.8, 2.7
	SD, SE	4129.77, 973.40	3902.06, 737.42	3946.98, 581.95	16.58, 3.13	2.25, 0.39	11.87, 1.52
	MEDIAN	5004.8	4330.9	4816.4	4.1	1.2	1.8
	MIN, MAX	53.6, 18644.1	349.1, 18285.0	53.6, 18644.1	1.0, 66.3	1.0, 11.3	1.0, 66.3
	5%, 95%	53.6, 18644.1	835.5, 11100.3	745.1, 11100.3	1.0, 61.9	1.0, 7.6	1.0, 18.6
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	12.3, 12.3	12.3, 12.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	12.3	12.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	12.3, 12.3	12.3, 12.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3815.1, 2575.8	3815.1, 2575.8	3.0, 3.0	NA, NA	3.0, 3.0
	SD, SE	NA, NA	3895.94, 2249.32	3895.94, 2249.32	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2306.2	2306.2	3.0	NA	3.0
	MIN, MAX	NA, NA	899.3, 8239.8	899.3, 8239.8	3.0, 3.0	NA, NA	3.0, 3.0
	5%, 95%	NA, NA	899.3, 8239.8	899.3, 8239.8	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537901

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 322 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11511.1, 11511.1	11511.1, 11511.1	16.1, 16.1	10.9, 9.3	12.6, 11.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	8.06, 5.70	6.44, 3.72
	MEDIAN	NA	11511.1	11511.1	16.1	10.9	16.1
	MIN, MAX	NA, NA	11511.1, 11511.1	11511.1, 11511.1	16.1, 16.1	5.2, 16.6	5.2, 16.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 16.6	5.2, 16.6
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	28213.3, 16081.4	24435.6, 17189.7	25913.9, 16747.2	45.6, 18.5	12.0, 8.4	27.4, 12.1
	SD, SE	31254.60, 7366.79	18181.60, 3436.00	23892.50, 3522.75	94.00, 17.76	16.15, 2.81	66.34, 8.49
	MEDIAN	20513.4	20663.7	20639.0	14.6	5.2	7.8
	MIN, MAX	296.6, 138305.1	351.2, 78906.6	296.6, 138305.1	5.2, 500.0	5.2, 93.7	5.2, 500.0
	5%, 95%	296.6, 138305.0	3133.2, 63952.2	3133.2, 63952.2	5.2, 111.9	5.2, 30.7	5.2, 93.7
	BLQ Values Included	0	0	0	8	15	23
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	74.9, 74.9	74.9, 74.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	74.9	74.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	74.9, 74.9	74.9, 74.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	18976.9, 12172.8	18976.9, 12172.8	25.5, 25.5	NA, NA	25.5, 25.5
	SD, SE	NA, NA	17110.40, 9878.68	17110.40, 9878.68	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	17161.6	17161.6	25.5	NA	25.5
	MIN, MAX	NA, NA	2846.6, 36922.6	2846.6, 36922.6	25.5, 25.5	NA, NA	25.5, 25.5
	5%, 95%	NA, NA	2846.6, 36922.6	2846.6, 36922.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537902

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC RACE
(Page 323 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	14120.9, 14120.9	14120.9, 14120.9	22.9, 22.9	15.1, 11.4	17.7, 14.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	14.00, 9.90	10.88, 6.28
	MEDIAN	NA	14120.9	14120.9	22.9	15.1	22.9
	MIN, MAX	NA, NA	14120.9, 14120.9	14120.9, 14120.9	22.9, 22.9	5.2, 25.0	5.2, 25.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 25.0	5.2, 25.0
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	29965.1, 18637.5	33499.6, 23917.2	32085.8, 21646.2	72.2, 22.2	14.5, 9.5	41.0, 14.0
	SD, SE	27073.00, 6381.16	24752.20, 4763.57	25461.40, 3795.56	171.12, 32.34	19.09, 3.32	119.21, 15.26
	MEDIAN	24880.2	26328.7	25780.3	13.3	6.8	9.9
	MIN, MAX	279.9, 121371.9	1437.6, 84991.0	279.9, 121371.9	5.2, 881.4	5.2, 91.1	5.2, 881.4
	5%, 95%	279.9, 121372.0	5039.1, 84729.3	4198.8, 84729.3	5.2, 299.7	5.2, 70.8	5.2, 136.3
	BLQ Values Included	0	0	0	2	13	15
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	52.0, 52.0	52.0, 52.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	52.0	52.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	52.0, 52.0	52.0, 52.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	22062.6, 13676.0	22062.6, 13676.0	13.0, 13.0	NA, NA	13.0, 13.0
	SD, SE	NA, NA	26055.70, 15043.20	26055.70, 15043.20	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7529.8	7529.8	13.0	NA	13.0
	MIN, MAX	NA, NA	6514.7, 52143.4	6514.7, 52143.4	13.0, 13.0	NA, NA	13.0, 13.0
	5%, 95%	NA, NA	6514.7, 52143.4	6514.7, 52143.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537903

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17274.0, 17274.0	17274.0, 17274.0	13.5, 13.5	8.9, 8.1	10.4, 9.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	5.16, 3.65	4.53, 2.62
	MEDIAN	NA	17274.0	17274.0	13.5	8.9	12.5
	MIN, MAX	NA, NA	17274.0, 17274.0	17274.0, 17274.0	13.5, 13.5	5.2, 12.5	5.2, 13.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 12.5	5.2, 13.5
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	25136.6, 15089.8	28352.6, 21406.3	27050.9, 18581.2	37.4, 16.9	10.0, 7.8	22.6, 11.1
	SD, SE	20762.10, 5035.55	24173.00, 4834.59	22645.60, 3494.29	69.45, 13.13	8.61, 1.50	48.99, 6.27
	MEDIAN	21947.3	21210.5	21578.9	13.6	5.2	6.2
	MIN, MAX	259.6, 77875.4	3659.8, 121774.7	259.6, 121774.7	5.2, 359.5	5.2, 35.9	5.2, 359.5
	5%, 95%	259.6, 77875.4	4869.0, 59068.1	3659.8, 64930.8	5.2, 113.9	5.2, 29.7	5.2, 81.2
	BLQ Values Included	0	0	0	7	18	25
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	65.0, 65.0	65.0, 65.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	65.0	65.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	65.0, 65.0	65.0, 65.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	18510.4, 12787.0	18510.4, 12787.0	7.8, 7.8	NA, NA	7.8, 7.8
	SD, SE	NA, NA	18519.60, 10692.30	18519.60, 10692.30	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	11305.6	11305.6	7.8	NA	7.8
	MIN, MAX	NA, NA	4675.9, 39549.6	4675.9, 39549.6	7.8, 7.8	NA, NA	7.8, 7.8
	5%, 95%	NA, NA	4675.9, 39549.6	4675.9, 39549.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 325 of ?)

Lab: Harrogate
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	14302.0, 14302.0	14302.0, 14302.0	17.5, 17.5	11.6, 9.7	13.6, 11.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	9.05, 6.40	7.25, 4.19
	MEDIAN	NA	14302.0	14302.0	17.5	11.6	17.5
	MIN, MAX	NA, NA	14302.0, 14302.0	14302.0, 14302.0	17.5, 17.5	5.2, 18.0	5.2, 18.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 18.0	5.2, 18.0
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	28104.0, 18394.8	28043.8, 21123.7	28067.3, 20010.7	51.7, 22.5	12.2, 9.2	30.3, 13.9
	SD, SE	21487.20, 5064.58	20302.50, 3836.80	20536.20, 3027.89	86.24, 16.30	11.71, 2.04	61.76, 7.91
	MEDIAN	26040.0	22533.3	25059.3	21.5	6.1	9.5
	MIN, MAX	278.7, 97005.2	1816.2, 95136.9	278.7, 97005.2	5.2, 344.8	5.2, 58.8	5.2, 344.8
	5%, 95%	278.7, 97005.2	4347.1, 57754.9	3876.6, 57754.9	5.4, 322.2	5.2, 39.7	5.2, 96.8
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	64.0, 64.0	64.0, 64.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	64.0	64.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	64.0, 64.0	64.0, 64.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	19850.0, 13401.7	19850.0, 13401.7	15.4, 15.4	NA, NA	15.4, 15.4
	SD, SE	NA, NA	20270.70, 11703.30	20270.70, 11703.30	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	11999.0	11999.0	15.4	NA	15.4
	MIN, MAX	NA, NA	4679.1, 42871.9	4679.1, 42871.9	15.4, 15.4	NA, NA	15.4, 15.4
	5%, 95%	NA, NA	4679.1, 42871.9	4679.1, 42871.9	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 326 of ?)

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2380.5, 2380.5	2380.5, 2380.5	2.6, 2.6	1.3, 1.2	1.7, 1.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.35, 0.25	0.82, 0.47
	MEDIAN	NA	2380.5	2380.5	2.6	1.3	1.5
	MIN, MAX	NA, NA	2380.5, 2380.5	2380.5, 2380.5	2.6, 2.6	1.0, 1.5	1.0, 2.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.5	1.0, 2.6
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3751.4, 2167.4	3510.3, 2462.2	3604.6, 2342.3	7.2, 3.2	2.1, 1.5	4.4, 2.1
	SD, SE	3939.23, 928.49	2776.11, 524.64	3240.43, 477.78	14.46, 2.73	2.97, 0.52	10.26, 1.31
	MEDIAN	3027.7	3397.5	3368.5	2.9	1.1	1.3
	MIN, MAX	30.1, 17333.8	52.2, 12964.7	30.1, 17333.8	1.0, 77.2	1.0, 17.7	1.0, 77.2
	5%, 95%	30.1, 17333.8	445.6, 9882.6	445.6, 9882.6	1.0, 16.5	1.0, 4.9	1.0, 16.4
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	10.2, 10.2	10.2, 10.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	10.2	10.2
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	10.2, 10.2	10.2, 10.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3097.6, 1876.6	3097.6, 1876.6	4.4, 4.4	NA, NA	4.4, 4.4
	SD, SE	NA, NA	3063.91, 1768.95	3063.91, 1768.95	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2430.5	2430.5	4.4	NA	4.4
	MIN, MAX	NA, NA	422.2, 6440.1	422.2, 6440.1	4.4, 4.4	NA, NA	4.4, 4.4
	5%, 95%	NA, NA	422.2, 6440.1	422.2, 6440.1	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1911.3, 1911.3	1911.3, 1911.3	2.2, 2.2	2.8, 2.1	2.6, 2.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.47, 1.75	1.78, 1.03
	MEDIAN	NA	1911.3	1911.3	2.2	2.8	2.2
	MIN, MAX	NA, NA	1911.3, 1911.3	1911.3, 1911.3	2.2, 2.2	1.0, 4.5	1.0, 4.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 4.5	1.0, 4.5
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	4429.1, 2668.3	5096.1, 3538.7	4829.3, 3160.8	11.2, 3.7	2.2, 1.6	6.4, 2.4
	SD, SE	4222.63, 995.28	3949.74, 760.13	4027.00, 600.31	26.20, 4.95	2.80, 0.49	18.26, 2.34
	MEDIAN	3357.9	4054.4	3464.4	2.6	1.2	1.6
	MIN, MAX	26.9, 18865.3	219.4, 13348.8	26.9, 18865.3	1.0, 135.0	1.0, 15.9	1.0, 135.0
	5%, 95%	26.9, 18865.3	731.1, 13308.1	692.4, 13308.1	1.0, 45.6	1.0, 6.9	1.0, 21.4
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	7.0, 7.0	7.0, 7.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	7.0	7.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	7.0, 7.0	7.0, 7.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3500.5, 2090.2	3500.5, 2090.2	2.4, 2.4	NA, NA	2.4, 2.4
	SD, SE	NA, NA	4259.03, 2458.95	4259.03, 2458.95	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1048.0	1048.0	2.4	NA	2.4
	MIN, MAX	NA, NA	1035.1, 8418.4	1035.1, 8418.4	2.4, 2.4	NA, NA	2.4, 2.4
	5%, 95%	NA, NA	1035.1, 8418.4	1035.1, 8418.4	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537907

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2455.4, 2455.4	2455.4, 2455.4	2.0, 2.0	1.0, 1.0	1.3, 1.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.58, 0.33
	MEDIAN	NA	2455.4	2455.4	2.0	1.0	1.0
	MIN, MAX	NA, NA	2455.4, 2455.4	2455.4, 2455.4	2.0, 2.0	1.0, 1.0	1.0, 2.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 1.0	1.0, 2.0
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	3384.2, 2057.2	3929.6, 3010.9	3708.9, 2580.7	5.8, 2.9	1.7, 1.4	3.6, 1.9
	SD, SE	2434.95, 590.56	3149.70, 629.94	2862.58, 441.71	10.65, 2.01	1.33, 0.23	7.50, 0.96
	MEDIAN	3560.9	3089.2	3269.8	2.5	1.0	1.3
	MIN, MAX	20.4, 9253.1	525.1, 15599.2	20.4, 15599.2	1.0, 56.0	1.0, 5.8	1.0, 56.0
	5%, 95%	20.4, 9253.1	627.6, 8394.0	525.1, 8394.0	1.0, 17.1	1.0, 5.6	1.0, 10.9
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	9.7, 9.7	9.7, 9.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	9.7	9.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	9.7, 9.7	9.7, 9.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3023.0, 2123.9	3023.0, 2123.9	1.3, 1.3	NA, NA	1.3, 1.3
	SD, SE	NA, NA	3104.26, 1792.25	3104.26, 1792.25	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1520.9	1520.9	1.3	NA	1.3
	MIN, MAX	NA, NA	955.5, 6592.6	955.5, 6592.6	1.3, 1.3	NA, NA	1.3, 1.3
	5%, 95%	NA, NA	955.5, 6592.6	955.5, 6592.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537908

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2249.1, 2249.1	2249.1, 2249.1	2.3, 2.3	1.7, 1.5	1.9, 1.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.92, 0.65	0.75, 0.43
	MEDIAN	NA	2249.1	2249.1	2.3	1.7	2.3
	MIN, MAX	NA, NA	2249.1, 2249.1	2249.1, 2249.1	2.3, 2.3	1.0, 2.3	1.0, 2.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	1.0, 2.3	1.0, 2.3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3908.9, 2541.6	4078.2, 3045.4	4011.9, 2837.3	8.1, 3.7	2.0, 1.6	4.8, 2.4
	SD, SE	2969.07, 699.82	2991.51, 565.34	2950.71, 435.06	13.39, 2.53	1.72, 0.30	9.57, 1.22
	MEDIAN	3787.3	3393.2	3564.8	3.3	1.3	1.7
	MIN, MAX	25.8, 13647.0	265.6, 13970.9	25.8, 13970.9	1.0, 52.6	1.0, 8.8	1.0, 52.6
	5%, 95%	25.8, 13647.0	601.4, 8965.5	601.4, 8965.5	1.0, 51.5	1.0, 6.6	1.0, 14.3
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	9.0, 9.0	9.0, 9.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	9.0	9.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	9.0, 9.0	9.0, 9.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3207.1, 2126.1	3207.1, 2126.1	2.7, 2.7	NA, NA	2.7, 2.7
	SD, SE	NA, NA	3441.59, 1987.00	3441.59, 1987.00	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1662.2	1662.2	2.7	NA	2.7
	MIN, MAX	NA, NA	808.6, 7150.4	808.6, 7150.4	2.7, 2.7	NA, NA	2.7, 2.7
	5%, 95%	NA, NA	808.6, 7150.4	808.6, 7150.4	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537909

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 330 of ?)

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12385.7, 12385.7	12385.7, 12385.7	13.5, 13.5	6.5, 6.4	8.8, 8.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.84, 1.30	4.25, 2.45
	MEDIAN	NA	12385.7	12385.7	13.5	6.5	7.8
	MIN, MAX	NA, NA	12385.7, 12385.7	12385.7, 12385.7	13.5, 13.5	5.2, 7.8	5.2, 13.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 7.8	5.2, 13.5
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	19518.5, 11277.0	18264.0, 12810.7	18754.9, 12187.2	37.3, 16.5	10.8, 7.9	23.0, 11.0
	SD, SE	20495.80, 4830.91	14444.10, 2729.68	16860.00, 2485.87	75.24, 14.22	15.43, 2.69	53.40, 6.84
	MEDIAN	15752.9	17676.9	17526.3	14.9	5.7	6.8
	MIN, MAX	156.6, 90187.8	271.6, 67455.3	156.6, 90187.8	5.2, 401.7	5.2, 92.1	5.2, 401.7
	5%, 95%	156.6, 90187.8	2318.5, 51419.2	2318.5, 51419.2	5.2, 85.8	5.2, 25.5	5.2, 85.3
	BLQ Values Included	0	0	0	7	15	22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	53.1, 53.1	53.1, 53.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	53.1	53.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	53.1, 53.1	53.1, 53.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	16116.8, 9763.9	16116.8, 9763.9	22.9, 22.9	NA, NA	22.9, 22.9
	SD, SE	NA, NA	15941.50, 9203.83	15941.50, 9203.83	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	12645.9	12645.9	22.9	NA	22.9
	MIN, MAX	NA, NA	2196.7, 33507.8	2196.7, 33507.8	22.9, 22.9	NA, NA	22.9, 22.9
	5%, 95%	NA, NA	2196.7, 33507.8	2196.7, 33507.8	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537910

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	9944.5, 9944.5	9944.5, 9944.5	11.4, 11.4	14.3, 11.0	13.3, 11.2
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	12.87, 9.10	9.25, 5.34
	MEDIAN	NA	9944.5	9944.5	11.4	14.3	11.4
	MIN, MAX	NA, NA	9944.5, 9944.5	9944.5, 9944.5	11.4, 11.4	5.2, 23.4	5.2, 23.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 23.4	5.2, 23.4
	BLQ Values Included	NA	0	0	0	1	1
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	23044.8, 13883.4	26515.0, 18411.8	25126.9, 16445.9	58.4, 19.1	11.6, 8.4	33.1, 12.3
	SD, SE	21970.40, 5178.46	20550.50, 3954.95	20952.50, 3123.41	136.30, 25.76	14.56, 2.53	95.01, 12.16
	MEDIAN	17470.9	21095.0	18025.3	13.3	6.2	8.3
	MIN, MAX	140.0, 98156.2	1141.5, 69453.8	140.0, 98156.2	5.2, 702.4	5.2, 82.7	5.2, 702.4
	5%, 95%	140.0, 98156.2	3803.9, 69242.0	3602.6, 69242.0	5.2, 237.3	5.2, 35.9	5.2, 111.3
	BLQ Values Included	0	0	0	3	14	17
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	36.4, 36.4	36.4, 36.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	36.4	36.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	36.4, 36.4	36.4, 36.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	18213.1, 10875.3	18213.1, 10875.3	12.5, 12.5	NA, NA	12.5, 12.5
	SD, SE	NA, NA	22159.70, 12793.90	22159.70, 12793.90	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5452.7	5452.7	12.5	NA	12.5
	MIN, MAX	NA, NA	5385.6, 43800.9	5385.6, 43800.9	12.5, 12.5	NA, NA	12.5, 12.5
	5%, 95%	NA, NA	5385.6, 43800.9	5385.6, 43800.9	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537911

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12775.4, 12775.4	12775.4, 12775.4	10.4, 10.4	5.2, 5.2	6.9, 6.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	3.00, 1.73
	MEDIAN	NA	12775.4	12775.4	10.4	5.2	5.2
	MIN, MAX	NA, NA	12775.4, 12775.4	12775.4, 12775.4	10.4, 10.4	5.2, 5.2	5.2, 10.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 5.2	5.2, 10.4
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	17608.0, 10703.4	20445.9, 15665.5	19297.2, 13427.3	30.0, 14.8	8.8, 7.3	18.6, 10.1
	SD, SE	12669.00, 3072.69	16387.90, 3277.57	14894.00, 2298.19	55.44, 10.48	6.90, 1.20	39.01, 5.00
	MEDIAN	18527.4	16073.1	17012.5	12.8	5.2	6.8
	MIN, MAX	106.1, 48143.9	2732.1, 81162.6	106.1, 81162.6	5.2, 291.4	5.2, 30.2	5.2, 291.4
	5%, 95%	106.1, 48143.9	3265.4, 43674.0	2732.1, 43674.0	5.2, 89.0	5.2, 29.1	5.2, 56.7
	BLQ Values Included	0	0	0	8	21	29
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	50.5, 50.5	50.5, 50.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	50.5	50.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	50.5, 50.5	50.5, 50.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	15728.7, 11050.5	15728.7, 11050.5	6.8, 6.8	NA, NA	6.8, 6.8
	SD, SE	NA, NA	16151.50, 9325.06	16151.50, 9325.06	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7913.2	7913.2	6.8	NA	6.8
	MIN, MAX	NA, NA	4971.5, 34301.3	4971.5, 34301.3	6.8, 6.8	NA, NA	6.8, 6.8
	5%, 95%	NA, NA	4971.5, 34301.3	4971.5, 34301.3	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

PM3003537912

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 333 of ?)

Lab: Harrogate
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11701.9, 11701.9	11701.9, 11701.9	11.8, 11.8	8.7, 7.9	9.7, 9.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	4.88, 3.45	3.90, 2.25
	MEDIAN	NA	11701.9	11701.9	11.8	8.7	11.8
	MIN, MAX	NA, NA	11701.9, 11701.9	11701.9, 11701.9	11.8, 11.8	5.2, 12.1	5.2, 12.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.2, 12.1	5.2, 12.1
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	20338.0, 13223.8	21218.7, 15844.9	20874.1, 14762.5	41.9, 19.3	10.4, 8.4	24.9, 12.3
	SD, SE	15448.10, 3641.14	15564.80, 2941.47	15352.60, 2263.61	69.68, 13.17	8.91, 1.55	49.78, 6.37
	MEDIAN	19705.4	17654.8	18547.7	17.1	6.6	9.0
	MIN, MAX	134.2, 71005.4	1381.7, 72690.6	134.2, 72690.6	5.2, 273.7	5.2, 45.6	5.2, 273.7
	5%, 95%	134.2, 71005.4	3129.3, 46647.3	3129.3, 46647.3	5.2, 268.1	5.2, 34.5	5.2, 74.6
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	46.7, 46.7	46.7, 46.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	46.7	46.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	46.7, 46.7	46.7, 46.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	16686.2, 11061.8	16686.2, 11061.8	14.1, 14.1	NA, NA	14.1, 14.1
	SD, SE	NA, NA	17906.60, 10338.40	17906.60, 10338.40	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	8648.2	8648.2	14.1	NA	14.1
	MIN, MAX	NA, NA	4207.0, 37203.3	4207.0, 37203.3	14.1, 14.1	NA, NA	14.1, 14.1
	5%, 95%	NA, NA	4207.0, 37203.3	4207.0, 37203.3	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537913

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 334 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	12.7	NA	12.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	15881.3, 12002.3	3716.4, 3522.0	9798.9, 6501.7	NA, NA	12.7, 12.7	12.7, 12.7
	SD, SE	12560.30, 7251.68	1519.43, 877.25	10412.60, 4250.94	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	14410.2	3272.1	4765.0	NA	12.7	12.7
	MIN, MAX	4121.4, 29112.4	2468.7, 5408.5	2468.7, 29112.4	NA, NA	12.7, 12.7	12.7, 12.7
	5%, 95%	4121.4, 29112.4	2468.7, 5408.5	2468.7, 29112.4	NA, NA	12.7, 12.7	12.7, 12.7
	BLQ Values Included	0	0	0	NA	2	2

PM3003537914

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	12.7	NA	12.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	3	4
	MEAN, GEO MEAN	13046.6, 10206.2	4821.8, 4348.3	8934.2, 6661.8	12.7, 12.7	24.9, 20.0	21.9, 17.8
	SD, SE	9005.77, 5199.48	2813.16, 1624.18	7476.72, 3052.36	NA, NA	21.19, 12.23	18.35, 9.18
	MEDIAN	14296.8	3453.4	5769.3	12.7	12.7	12.7
	MIN, MAX	3481.1, 21362.0	2954.7, 8057.4	2954.7, 21362.0	12.7, 12.7	12.7, 49.4	12.7, 49.4
	5%, 95%	3481.1, 21362.0	2954.7, 8057.4	2954.7, 21362.0	NA, NA	12.7, 49.4	12.7, 49.4
	BLQ Values Included	0	0	0	1	2	3

PM3003537915

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	12.7	NA	12.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	5553.6, 4245.8	5049.5, 4741.8	5251.1, 4536.8	12.7, 12.7	12.7, 12.7	12.7, 12.7
	SD, SE	5062.67, 3579.85	1969.90, 1137.32	2902.43, 1298.01	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	5553.6	5824.0	5824.0	12.7	12.7	12.7
	MIN, MAX	1973.7, 9133.4	2810.1, 6514.5	1973.7, 9133.4	12.7, 12.7	12.7, 12.7	12.7, 12.7
	5%, 95%	1973.7, 9133.4	2810.1, 6514.5	1973.7, 9133.4	12.7, 12.7	12.7, 12.7	12.7, 12.7
	BLQ Values Included	0	0	0	3	3	6

PM3003537916

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Nicotine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	12.7	NA	12.7
	MIN, MAX	NA, NA	NA, NA	NA, NA	12.7, 12.7	NA, NA	12.7, 12.7
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	12471.6, 9691.8	4529.3, 4244.4	8500.5, 6413.7	12.7, 12.7	16.8, 15.9	14.7, 14.2
	SD, SE	8496.37, 4905.38	1980.61, 1143.50	7026.29, 2868.47	0.00, 0.00	7.04, 4.07	4.98, 2.03
	MEDIAN	14353.5	4183.2	5421.7	12.7	12.7	12.7
	MIN, MAX	3192.1, 19869.3	2744.5, 6660.1	2744.5, 19869.3	12.7, 12.7	12.7, 24.9	12.7, 24.9
	5%, 95%	3192.1, 19869.3	2744.5, 6660.1	2744.5, 19869.3	12.7, 12.7	12.7, 24.9	12.7, 24.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537917

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 338 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.1	NA	2.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	2575.9, 1946.8	602.8, 571.3	1589.4, 1054.6	NA, NA	2.1, 2.1	2.1, 2.1
	SD, SE	2037.26, 1176.21	246.49, 142.31	1688.92, 689.50	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	2337.3	530.7	772.9	NA	2.1	2.1
	MIN, MAX	668.5, 4722.0	400.4, 877.3	400.4, 4722.0	NA, NA	2.1, 2.1	2.1, 2.1
	5%, 95%	668.5, 4722.0	400.4, 877.3	400.4, 4722.0	NA, NA	2.1, 2.1	2.1, 2.1
	BLQ Values Included	0	0	0	NA	2	2

PM3003537918

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 339 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.1	NA	2.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	3	4
	MEAN, GEO MEAN	2116.1, 1655.4	782.1, 705.3	1449.1, 1080.5	2.1, 2.1	4.1, 3.3	3.6, 2.9
	SD, SE	1460.74, 843.36	456.28, 263.43	1212.72, 495.09	NA, NA	3.41, 1.97	2.95, 1.48
	MEDIAN	2318.9	560.1	935.8	2.1	2.1	2.1
	MIN, MAX	564.6, 3464.9	479.3, 1306.9	479.3, 3464.9	2.1, 2.1	2.1, 8.0	2.1, 8.0
	5%, 95%	564.6, 3464.9	479.3, 1306.9	479.3, 3464.9	NA, NA	2.1, 8.0	2.1, 8.0
	BLQ Values Included	0	0	0	1	2	3

PM3003537919

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 340 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.1	NA	2.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	900.8, 688.6	819.1, 769.1	851.7, 735.9	2.1, 2.1	2.1, 2.1	2.1, 2.1
	SD, SE	821.16, 580.65	319.54, 184.49	470.78, 210.54	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	900.8	944.7	944.7	2.1	2.1	2.1
	MIN, MAX	320.1, 1481.4	455.8, 1056.7	320.1, 1481.4	2.1, 2.1	2.1, 2.1	2.1, 2.1
	5%, 95%	320.1, 1481.4	455.8, 1056.7	320.1, 1481.4	2.1, 2.1	2.1, 2.1	2.1, 2.1
	BLQ Values Included	0	0	0	3	3	6

PM3003537920

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 341 of ?)

Lab: INBIFO
Biomarker: Total Nicotine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.1	NA	2.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.1, 2.1	NA, NA	2.1, 2.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	2022.9, 1571.9	734.7, 688.5	1378.8, 1040.3	2.1, 2.1	2.8, 2.6	2.4, 2.3
	SD, SE	1378.14, 795.67	321.25, 185.48	1139.66, 465.26	0.00, 0.00	1.15, 0.67	0.82, 0.33
	MEDIAN	2328.1	678.5	879.4	2.1	2.1	2.1
	MIN, MAX	517.7, 3222.8	445.2, 1080.3	445.2, 3222.8	2.1, 2.1	2.1, 4.1	2.1, 4.1
	5%, 95%	517.7, 3222.8	445.2, 1080.3	445.2, 3222.8	2.1, 2.1	2.1, 4.1	2.1, 4.1

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537921

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 342 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	3.4, 3.4	NA, NA	3.4, 3.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	3.4	NA	3.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	3.4, 3.4	NA, NA	3.4, 3.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	12271.5, 9840.3	2122.6, 2006.9	7197.1, 4444.0	3.4, 3.4	3.4, 3.4	3.4, 3.4
	SD, SE	8510.73, 4913.67	871.69, 503.27	7757.37, 3166.93	NA, NA	NA, NA	0.00, 0.00
	MEDIAN	12357.7	1940.2	3394.6	3.4	3.4	3.4
	MIN, MAX	3718.0, 20738.8	1356.6, 3071.1	1356.6, 20738.8	3.4, 3.4	3.4, 3.4	3.4, 3.4
	5%, 95%	3718.0, 20738.8	1356.6, 3071.1	1356.6, 20738.8	NA, NA	NA, NA	3.4, 3.4
	BLQ Values Included	0	0	0	1	1	2

PM3003537922

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 343 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	9033.2, 6684.7	3079.6, 2638.5	6056.4, 4199.7	NA, NA	3.4, 3.4	3.4, 3.4
	SD, SE	6416.07, 3704.32	2203.98, 1272.47	5389.15, 2200.11	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	10778.2	1809.1	3774.8	NA	3.4	3.4
	MIN, MAX	1925.1, 14396.2	1805.1, 5624.5	1805.1, 14396.2	NA, NA	3.4, 3.4	3.4, 3.4
	5%, 95%	1925.1, 14396.2	1805.1, 5624.5	1805.1, 14396.2	NA, NA	3.4, 3.4	3.4, 3.4
	BLQ Values Included	0	0	0	NA	2	2

PM3003537923

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 344 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	3417.6, 2856.3	3389.0, 3052.9	3400.4, 2972.7	3.4, 3.4	3.4, 3.4	3.4, 3.4
	SD, SE	2653.91, 1876.60	1624.09, 937.67	1754.96, 784.84	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	3417.6	4113.9	4113.9	3.4	3.4	3.4
	MIN, MAX	1541.0, 5294.2	1528.7, 4524.4	1528.7, 5294.2	3.4, 3.4	3.4, 3.4	3.4, 3.4
	5%, 95%	1541.0, 5294.2	1528.7, 4524.4	1528.7, 5294.2	3.4, 3.4	3.4, 3.4	3.4, 3.4
	BLQ Values Included	0	0	0	2	2	4

PM3003537924

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	3.4, 3.4	NA, NA	3.4, 3.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	3.4	NA	3.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	3.4, 3.4	NA, NA	3.4, 3.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	9146.4, 7200.5	2863.7, 2640.9	6005.1, 4360.7	3.4, 3.4	3.4, 3.4	3.4, 3.4
	SD, SE	5924.46, 3420.49	1355.68, 782.70	5159.10, 2106.19	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	11568.0	2756.6	3513.2	3.4	3.4	3.4
	MIN, MAX	2394.7, 13476.4	1564.8, 4269.8	1564.8, 13476.4	3.4, 3.4	3.4, 3.4	3.4, 3.4
	5%, 95%	2394.7, 13476.4	1564.8, 4269.8	1564.8, 13476.4	3.4, 3.4	3.4, 3.4	3.4, 3.4

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537925

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 346 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.6, 0.6	NA, NA	0.6, 0.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.6	NA	0.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.6, 0.6	NA, NA	0.6, 0.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	1	1	2
	MEAN, GEO MEAN	1990.4, 1596.1	344.3, 325.5	1167.4, 720.8	0.6, 0.6	0.6, 0.6	0.6, 0.6
	SD, SE	1380.40, 796.98	141.39, 81.63	1258.24, 513.67	NA, NA	NA, NA	0.00, 0.00
	MEDIAN	2004.4	314.7	550.6	0.6	0.6	0.6
	MIN, MAX	603.1, 3363.8	220.0, 498.1	220.0, 3363.8	0.6, 0.6	0.6, 0.6	0.6, 0.6
	5%, 95%	603.1, 3363.8	220.0, 498.1	220.0, 3363.8	NA, NA	NA, NA	0.6, 0.6
	BLQ Values Included	0	0	0	1	1	2

PM3003537926

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 347 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	0	2	2
	MEAN, GEO MEAN	1465.2, 1084.3	499.5, 427.9	982.4, 681.2	NA, NA	0.6, 0.6	0.6, 0.6
	SD, SE	1040.67, 600.83	357.50, 206.40	874.12, 356.86	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	1748.2	293.4	612.3	NA	0.6	0.6
	MIN, MAX	312.3, 2335.1	292.8, 912.3	292.8, 2335.1	NA, NA	0.6, 0.6	0.6, 0.6
	5%, 95%	312.3, 2335.1	292.8, 912.3	292.8, 2335.1	NA, NA	0.6, 0.6	0.6, 0.6
	BLQ Values Included	0	0	0	NA	2	2

PM3003537927

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 348 of ?)

Lab: INBIFO
Biomarker: Free Nicotine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	2	2	4
	MEAN, GEO MEAN	554.4, 463.3	549.7, 495.2	551.6, 482.2	0.6, 0.6	0.6, 0.6	0.6, 0.6
	SD, SE	430.42, 304.35	263.42, 152.09	284.63, 127.29	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	554.4	667.3	667.3	0.6	0.6	0.6
	MIN, MAX	250.0, 858.7	248.0, 733.9	248.0, 858.7	0.6, 0.6	0.6, 0.6	0.6, 0.6
	5%, 95%	250.0, 858.7	248.0, 733.9	248.0, 858.7	0.6, 0.6	0.6, 0.6	0.6, 0.6
	BLQ Values Included	0	0	0	2	2	4

PM3003537928

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free Nicotine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.6, 0.6	NA, NA	0.6, 0.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.6	NA	0.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.6, 0.6	NA, NA	0.6, 0.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	1483.6, 1168.0	464.5, 428.3	974.0, 707.3	0.6, 0.6	0.6, 0.6	0.6, 0.6
	SD, SE	960.91, 554.78	219.92, 126.97	836.80, 341.62	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1876.3	447.1	569.9	0.6	0.6	0.6
	MIN, MAX	388.5, 2185.9	253.8, 692.6	253.8, 2185.9	0.6, 0.6	0.6, 0.6	0.6, 0.6
	5%, 95%	388.5, 2185.9	253.8, 692.6	253.8, 2185.9	0.6, 0.6	0.6, 0.6	0.6, 0.6

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537929

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	11.0	NA	11.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	18992.3, 11773.2	9720.5, 9427.6	14356.4, 10535.4	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	18911.30, 10918.40	2975.82, 1718.09	13129.60, 5360.14	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	14304.5	9064.9	11017.2	11.0	11.0	11.0
	MIN, MAX	2865.9, 39806.6	7127.2, 12969.5	2865.9, 39806.6	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	2865.9, 39806.6	7127.2, 12969.5	2865.9, 39806.6	11.0, 11.0	11.0, 11.0	11.0, 11.0
	BLQ Values Included	0	0	0	3	2	5

PM3003537930

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 351 of 7)

Lab: INBIFO
Biomarker: Total Cotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	11.0	NA	11.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	19069.8, 13837.6	10237.0, 10000.7	14653.4, 11763.7	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	13857.20, 8000.46	2815.53, 1625.55	10167.90, 4151.01	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	22533.0	8701.3	11093.9	11.0	11.0	11.0
	MIN, MAX	3809.5, 30867.0	8523.3, 13486.5	3809.5, 30867.0	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	3809.5, 30867.0	8523.3, 13486.5	3809.5, 30867.0	11.0, 11.0	11.0, 11.0	11.0, 11.0
	BLQ Values Included	0	0	0	3	3	6

PM3003537931

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	11.0	NA	11.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	11020.5, 5984.5	9272.5, 9086.7	9971.7, 7688.8	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	13087.10, 9253.95	2353.34, 1358.70	6819.34, 3049.70	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	11020.5	8330.8	8330.8	11.0	11.0	11.0
	MIN, MAX	1766.5, 20274.4	7535.9, 11950.9	1766.5, 20274.4	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	1766.5, 20274.4	7535.9, 11950.9	1766.5, 20274.4	11.0, 11.0	11.0, 11.0	11.0, 11.0
	BLQ Values Included	0	0	0	3	3	6

PM3003537932

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total Cotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	11.0	NA	11.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	11.0, 11.0	NA, NA	11.0, 11.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	17182.9, 11625.7	9743.4, 9522.3	13463.2, 10521.5	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	13792.60, 7963.16	2653.99, 1532.28	9773.22, 3989.90	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	18418.8	8374.7	10588.5	11.0	11.0	11.0
	MIN, MAX	2814.0, 30316.0	8053.1, 12802.3	2814.0, 30316.0	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	2814.0, 30316.0	8053.1, 12802.3	2814.0, 30316.0	11.0, 11.0	11.0, 11.0	11.0, 11.0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537933

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 354 of 7)

Lab: INBIFO
Biomarker: Total Cotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.9	NA	1.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	3346.5, 2074.5	1712.7, 1661.1	2529.6, 1856.3	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	3332.13, 1923.81	524.33, 302.72	2313.43, 944.45	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	2520.5	1597.2	1941.2	1.9	1.9	1.9
	MIN, MAX	505.0, 7013.9	1255.8, 2285.2	505.0, 7013.9	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	505.0, 7013.9	1255.8, 2285.2	505.0, 7013.9	1.9, 1.9	1.9, 1.9	1.9, 1.9
	BLQ Values Included	0	0	0	3	2	5

PM3003537934

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 355 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.9	NA	1.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3360.1, 2438.1	1803.8, 1762.1	2581.9, 2072.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	2441.67, 1409.70	496.08, 286.41	1791.59, 731.41	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	3970.3	1533.2	1954.8	1.9	1.9	1.9
	MIN, MAX	671.2, 5438.8	1501.8, 2376.3	671.2, 5438.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	671.2, 5438.8	1501.8, 2376.3	671.2, 5438.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	BLQ Values Included	0	0	0	3	3	6

PM3003537935

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 356 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.9	NA	1.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	2	3	5	3	3	6
	MEAN, GEO MEAN	1941.8, 1054.5	1633.8, 1601.1	1757.0, 1354.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	2305.88, 1630.50	414.64, 239.39	1201.54, 537.34	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1941.8	1467.9	1467.9	1.9	1.9	1.9
	MIN, MAX	311.3, 3572.3	1327.8, 2105.7	311.3, 3572.3	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	311.3, 3572.3	1327.8, 2105.7	311.3, 3572.3	1.9, 1.9	1.9, 1.9	1.9, 1.9
	BLQ Values Included	0	0	0	3	3	6

PM3003537936

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 357 of ?)

Lab: INBIFO
Biomarker: Total Cotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	1.9	NA	1.9
	MIN, MAX	NA, NA	NA, NA	NA, NA	1.9, 1.9	NA, NA	1.9, 1.9
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3027.6, 2048.4	1716.8, 1677.8	2372.2, 1853.9	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	2430.28, 1403.12	467.59, 269.96	1722.05, 703.03	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	3245.4	1475.6	1865.7	1.9	1.9	1.9
	MIN, MAX	495.8, 5341.7	1419.0, 2255.7	495.8, 5341.7	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	495.8, 5341.7	1419.0, 2255.7	495.8, 5341.7	1.9, 1.9	1.9, 1.9	1.9, 1.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537937

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 358 of 7)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	3.1, 3.1	NA, NA	3.1, 3.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	3.1	NA	3.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	3.1, 3.1	NA, NA	3.1, 3.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	6583.8, 5308.2	3693.7, 3619.1	5138.7, 4383.0	9.0, 5.9	3.1, 3.1	6.1, 4.3
	SD, SE	4959.84, 2863.57	939.49, 542.41	3563.54, 1454.81	10.28, 5.93	0.00, 0.00	7.27, 2.97
	MEDIAN	5463.6	3338.5	4048.8	3.1	3.1	3.1
	MIN, MAX	2279.8, 12007.9	2983.6, 4759.0	2279.8, 12007.9	3.1, 20.9	3.1, 3.1	3.1, 20.9
	5%, 95%	2279.8, 12007.9	2983.6, 4759.0	2279.8, 12007.9	3.1, 20.9	3.1, 3.1	3.1, 20.9
	BLQ Values Included	0	0	0	2	3	5

PM3003537938

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 359 of 7)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	3.1, 3.1	NA, NA	3.1, 3.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	3.1	NA	3.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	3.1, 3.1	NA, NA	3.1, 3.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	6439.9, 5581.3	4243.9, 4212.0	5341.9, 4848.5	3.1, 3.1	3.1, 3.1	3.1, 3.1
	SD, SE	3631.27, 2096.51	620.20, 358.07	2622.04, 1070.44	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	7090.1	4495.7	4597.2	3.1	3.1	3.1
	MIN, MAX	2527.5, 9702.2	3537.4, 4698.6	2527.5, 9702.2	3.1, 3.1	3.1, 3.1	3.1, 3.1
	5%, 95%	2527.5, 9702.2	3537.4, 4698.6	2527.5, 9702.2	3.1, 3.1	3.1, 3.1	3.1, 3.1
	BLQ Values Included	0	0	0	3	4	7

PM3003537939

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 360 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	4	7
	MEAN, GEO MEAN	4650.6, 3439.8	3602.1, 3500.7	4021.5, 3476.2	3.1, 3.1	3.1, 3.1	3.1, 3.1
	SD, SE	4426.13, 3129.75	1094.83, 632.10	2413.87, 1079.52	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	4650.6	3087.7	3087.7	3.1	3.1	3.1
	MIN, MAX	1520.8, 7780.3	2859.2, 4859.4	1520.8, 7780.3	3.1, 3.1	3.1, 3.1	3.1, 3.1
	5%, 95%	1520.8, 7780.3	2859.2, 4859.4	1520.8, 7780.3	3.1, 3.1	3.1, 3.1	3.1, 3.1
	BLQ Values Included	0	0	0	3	4	7

PM3003537940

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 361 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	3.1, 3.1	NA, NA	3.1, 3.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	3.1	NA	3.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	3.1, 3.1	NA, NA	3.1, 3.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	6072.1, 5067.8	3846.5, 3787.3	4959.3, 4381.0	5.1, 4.4	3.1, 3.1	3.9, 3.6
	SD, SE	3864.42, 2231.12	841.91, 486.07	2782.63, 1136.00	3.41, 1.97	0.00, 0.00	2.23, 0.84
	MEDIAN	6276.9	3640.6	4206.5	3.1	3.1	3.1
	MIN, MAX	2109.4, 9830.1	3126.7, 4772.3	2109.4, 9830.1	3.1, 9.0	3.1, 3.1	3.1, 9.0
	5%, 95%	2109.4, 9830.1	3126.7, 4772.3	2109.4, 9830.1	3.1, 9.0	3.1, 3.1	3.1, 9.0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537941

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 362 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.5, 0.5	NA, NA	0.5, 0.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.5	NA	0.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.5, 0.5	NA, NA	0.5, 0.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	1160.1, 935.3	650.8, 637.7	905.4, 772.3	1.6, 1.0	0.5, 0.5	1.0, 0.7
	SD, SE	873.93, 504.56	165.53, 95.57	627.91, 256.34	1.85, 1.07	0.00, 0.00	1.31, 0.53
	MEDIAN	962.7	588.2	713.4	0.5	0.5	0.5
	MIN, MAX	401.7, 2115.8	525.7, 838.5	401.7, 2115.8	0.5, 3.7	0.5, 0.5	0.5, 3.7
	5%, 95%	401.7, 2115.8	525.7, 838.5	401.7, 2115.8	0.5, 3.7	0.5, 0.5	0.5, 3.7
	BLQ Values Included	0	0	0	2	3	5

PM3003537942

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Labx INBIFO
Biomarker: Free Cotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.5, 0.5	NA, NA	0.5, 0.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.5	NA	0.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.5, 0.5	NA, NA	0.5, 0.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	1	NA	1
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	1134.7, 983.4	747.8, 742.1	941.2, 854.3	0.5, 0.5	0.5, 0.5	0.5, 0.5
	SD, SE	639.84, 369.41	109.27, 63.09	462.01, 188.61	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1249.3	792.1	810.0	0.5	0.5	0.5
	MIN, MAX	445.3, 1709.5	623.3, 827.9	445.3, 1709.5	0.5, 0.5	0.5, 0.5	0.5, 0.5
	5%, 95%	445.3, 1709.5	623.3, 827.9	445.3, 1709.5	0.5, 0.5	0.5, 0.5	0.5, 0.5
	BLQ Values Included	0	0	0	3	4	7

PM3003537943

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 364 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	4	7
	MEAN, GEO MEAN	819.5, 606.1	634.7, 616.8	708.6, 612.5	0.5, 0.5	0.5, 0.5	0.5, 0.5
	SD, SE	779.87, 551.45	192.88, 111.36	425.31, 190.20	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	819.5	544.1	544.1	0.5	0.5	0.5
	MIN, MAX	268.0, 1370.9	503.8, 856.2	268.0, 1370.9	0.5, 0.5	0.5, 0.5	0.5, 0.5
	5%, 95%	268.0, 1370.9	503.8, 856.2	268.0, 1370.9	0.5, 0.5	0.5, 0.5	0.5, 0.5
	BLQ Values Included	0	0	0	3	4	7

PM3003537944

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 365 of ?)

Lab: INBIFO
Biomarker: Free Cotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	0.5, 0.5	NA, NA	0.5, 0.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	0.5	NA	0.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	0.5, 0.5	NA, NA	0.5, 0.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	1069.9, 893.0	677.8, 667.3	873.9, 771.9	0.9, 0.7	0.5, 0.5	0.7, 0.6
	SD, SE	680.92, 393.13	148.36, 85.66	490.31, 200.17	0.64, 0.37	0.00, 0.00	0.42, 0.16
	MEDIAN	1106.0	641.5	741.2	0.5	0.5	0.5
	MIN, MAX	371.7, 1732.1	550.9, 840.9	371.7, 1732.1	0.5, 1.6	0.5, 0.5	0.5, 1.6
	5%, 95%	371.7, 1732.1	550.9, 840.9	371.7, 1732.1	0.5, 1.6	0.5, 0.5	0.5, 1.6

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537945

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 366 of 7)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	19663.7, 17523.9	17857.8, 17465.3	18760.8, 17494.6	28.5, 23.5	21.9, 18.5	24.5, 20.3
	SD, SE	9744.29, 5625.87	4337.31, 2504.15	6817.90, 2783.39	22.70, 16.05	16.45, 9.50	16.64, 7.44
	MEDIAN	24995.6	20281.3	20361.6	28.5	12.4	12.4
	MIN, MAX	8417.0, 25578.5	12850.4, 20441.8	8417.0, 25578.5	12.4, 44.5	12.4, 40.9	12.4, 44.5
	5%, 95%	8417.0, 25578.5	12850.4, 20441.8	8417.0, 25578.5	12.4, 44.5	12.4, 40.9	12.4, 44.5
	BLQ Values Included	0	0	0	1	2	3

PM3003537946

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 367 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	22250.3, 18298.4	17703.7, 16917.1	19977.0, 17594.2	22.2, 18.6	12.4, 12.4	18.3, 15.8
	SD, SE	15078.20, 8705.42	6696.93, 3866.47	10727.60, 4379.54	17.03, 9.83	0.00, 0.00	13.19, 5.90
	MEDIAN	21500.8	15546.0	18523.4	12.4	12.4	12.4
	MIN, MAX	7560.8, 37689.3	12351.6, 25213.5	7560.8, 37689.3	12.4, 41.9	12.4, 12.4	12.4, 41.9
	5%, 95%	7560.8, 37689.3	12351.6, 25213.5	7560.8, 37689.3	12.4, 41.9	12.4, 12.4	12.4, 41.9
	BLQ Values Included	0	0	0	2	2	4

PM3003537947

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	2	5
	MEAN, GEO MEAN	9886.9, 8143.2	14951.2, 12532.8	12925.5, 10547.5	12.4, 12.4	12.4, 12.4	12.4, 12.4
	SD, SE	7929.50, 5607.00	11304.30, 6526.57	9343.85, 4178.70	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	9886.9	9437.8	9437.8	12.4	12.4	12.4
	MIN, MAX	4279.9, 15493.9	7461.5, 27954.4	4279.9, 27954.4	12.4, 12.4	12.4, 12.4	12.4, 12.4
	5%, 95%	4279.9, 15493.9	7461.5, 27954.4	4279.9, 27954.4	12.4, 12.4	12.4, 12.4	12.4, 12.4
	BLQ Values Included	0	0	0	3	2	5

PM3003537948

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	19683.3, 16403.7	16837.6, 16021.8	18260.5, 16211.6	19.2, 17.2	21.9, 18.5	20.6, 17.8
	SD, SE	12469.60, 7199.31	6747.46, 3895.65	9101.47, 3715.66	11.84, 6.83	16.45, 9.50	12.90, 5.27
	MEDIAN	20663.4	14023.6	17343.5	12.4	12.4	12.4
	MIN, MAX	6752.6, 31633.9	11952.6, 24536.6	6752.6, 31633.9	12.4, 32.9	12.4, 40.9	12.4, 40.9
	5%, 95%	6752.6, 31633.9	11952.6, 24536.6	6752.6, 31633.9	12.4, 32.9	12.4, 40.9	12.4, 40.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537949

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	2	3	5
	MEAN, GEO MEAN	3779.4, 3368.1	3432.3, 3356.8	3605.8, 3362.4	5.5, 4.5	4.2, 3.6	4.7, 3.9
	SD, SE	1872.90, 1081.32	833.66, 481.32	1310.43, 534.98	4.38, 3.10	3.18, 1.83	3.21, 1.44
	MEDIAN	4804.2	3898.1	3913.5	5.5	2.4	2.4
	MIN, MAX	1617.7, 4916.2	2469.8, 3928.9	1617.7, 4916.2	2.4, 8.6	2.4, 7.9	2.4, 8.6
	5%, 95%	1617.7, 4916.2	2469.8, 3928.9	1617.7, 4916.2	2.4, 8.6	2.4, 7.9	2.4, 8.6
	BLQ Values Included	0	0	0	1	2	3

PM3003537950

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 371 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	2	5
	MEAN, GEO MEAN	4276.5, 3517.0	3402.6, 3251.4	3839.6, 3381.6	4.3, 3.6	2.4, 2.4	3.5, 3.1
	SD, SE	2898.04, 1673.18	1287.13, 743.12	2061.85, 841.75	3.29, 1.90	0.00, 0.00	2.55, 1.14
	MEDIAN	4132.5	2987.9	3560.2	2.4	2.4	2.4
	MIN, MAX	1453.2, 7243.9	2374.0, 4846.0	1453.2, 7243.9	2.4, 8.1	2.4, 2.4	2.4, 8.1
	5%, 95%	1453.2, 7243.9	2374.0, 4846.0	1453.2, 7243.9	2.4, 8.1	2.4, 2.4	2.4, 8.1
	BLQ Values Included	0	0	0	2	2	4

PM3003537951

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 372 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	2	3	5	3	2	5
	MEAN, GEO MEAN	1900.3, 1565.1	2873.6, 2408.8	2484.3, 2027.2	2.4, 2.4	2.4, 2.4	2.4, 2.4
	SD, SE	1524.03, 1077.65	2172.69, 1254.40	1795.88, 803.14	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1900.3	1813.9	1813.9	2.4	2.4	2.4
	MIN, MAX	822.6, 2977.9	1434.1, 5372.8	822.6, 5372.8	2.4, 2.4	2.4, 2.4	2.4, 2.4
	5%, 95%	822.6, 2977.9	1434.1, 5372.8	822.6, 5372.8	2.4, 2.4	2.4, 2.4	2.4, 2.4
	BLQ Values Included	0	0	0	3	2	5

PM3003537952

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 373 of ?)

Lab: INBIFO
Biomarker: Total 3-hydroxycotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Caucasian	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3783.1, 3152.8	3236.2, 3079.4	3509.7, 3115.9	3.7, 3.3	4.2, 3.6	4.0, 3.4
	SD, SE	2396.71, 1383.74	1296.85, 748.73	1749.33, 714.16	2.31, 1.33	3.18, 1.83	2.50, 1.02
	MEDIAN	3971.5	2695.3	3333.4	2.4	2.4	2.4
	MIN, MAX	1297.8, 6080.1	2297.3, 4715.9	1297.8, 6080.1	2.4, 6.4	2.4, 7.9	2.4, 7.9
	5%, 95%	1297.8, 6080.1	2297.3, 4715.9	1297.8, 6080.1	2.4, 6.4	2.4, 7.9	2.4, 7.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537953

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 374 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	10.6, 10.6	NA, NA	10.6, 10.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	10.6	NA	10.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	10.6, 10.6	NA, NA	10.6, 10.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	16696.1, 14940.9	14366.9, 14092.1	15531.5, 14510.3	14.5, 10.2	12.2, 9.7	13.2, 10.0
	SD, SE	8158.34, 4710.22	3268.60, 1887.13	5703.03, 2328.25	15.07, 8.70	8.60, 4.30	10.69, 4.04
	MEDIAN	21097.5	16158.5	16253.2	5.9	11.2	5.9
	MIN, MAX	7282.3, 21708.6	10594.2, 16347.9	7282.3, 21708.6	5.7, 31.9	4.9, 21.6	4.9, 31.9
	5%, 95%	7282.3, 21708.6	10594.2, 16347.9	7282.3, 21708.6	5.7, 31.9	4.9, 21.6	4.9, 31.9
	BLQ Values Included	0	0	0	0	0	0

PM3003537954

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 375 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	17.4, 17.4	NA, NA	17.4, 17.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	17.4	NA	17.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	17.4, 17.4	NA, NA	17.4, 17.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	2	4	6
	MEAN, GEO MEAN	17203.0, 13492.0	15228.1, 14505.1	16215.6, 13989.4	17.1, 13.4	9.4, 8.8	11.9, 10.1
	SD, SE	12805.30, 7393.14	5943.28, 3431.36	8993.85, 3671.72	14.92, 10.55	3.79, 1.90	8.30, 3.39
	MEDIAN	16061.2	13399.8	14730.5	17.1	8.6	8.6
	MIN, MAX	5006.9, 30541.0	10413.7, 21870.7	5006.9, 30541.0	6.5, 27.6	6.0, 14.3	6.0, 27.6
	5%, 95%	5006.9, 30541.0	10413.7, 21870.7	5006.9, 30541.0	6.5, 27.6	6.0, 14.3	6.0, 27.6
	BLQ Values Included	0	0	0	0	0	0

PM3003537955

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	12.5, 12.5	NA, NA	12.5, 12.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	12.5	NA	12.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	12.5, 12.5	NA, NA	12.5, 12.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	2	3	5	1	3	4
	MEAN, GEO MEAN	8140.5, 7014.7	12045.1, 10508.6	10483.2, 8939.9	7.0, 7.0	12.3, 11.6	11.0, 10.2
	SD, SE	5841.55, 4130.60	7912.77, 4568.44	6664.13, 2980.29	NA, NA	4.70, 2.71	4.66, 2.33
	MEDIAN	8140.5	8860.2	8860.2	7.0	12.4	10.0
	MIN, MAX	4009.9, 12271.1	6221.0, 21054.0	4009.9, 21054.0	7.0, 7.0	7.5, 16.9	7.0, 16.9
	5%, 95%	4009.9, 12271.1	6221.0, 21054.0	4009.9, 21054.0	NA, NA	7.5, 16.9	7.0, 16.9
	BLQ Values Included	0	0	0	0	0	0

PM3003537956

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	13.5, 13.5	NA, NA	13.5, 13.5
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	13.5	NA	13.5
	MIN, MAX	NA, NA	NA, NA	NA, NA	13.5, 13.5	NA, NA	13.5, 13.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	16011.5, 13273.5	13880.0, 13295.5	14945.7, 13284.5	11.4, 9.3	10.7, 9.8	11.0, 9.6
	SD, SE	10353.70, 5977.73	5163.80, 2981.32	7410.05, 3025.14	9.35, 5.40	4.99, 2.50	6.46, 2.44
	MEDIAN	16476.6	11810.8	14143.7	6.1	10.7	7.6
	MIN, MAX	5433.0, 26124.8	10071.7, 19757.5	5433.0, 26124.8	5.9, 22.2	5.5, 16.1	5.5, 22.2
	5%, 95%	5433.0, 26124.8	10071.7, 19757.5	5433.0, 26124.8	5.9, 22.2	5.5, 16.1	5.5, 22.2

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537957

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.0, 2.0	NA, NA	2.0, 2.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.0	NA	2.0
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.0, 2.0	NA, NA	2.0, 2.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3209.0, 2871.7	2761.3, 2708.5	2985.2, 2788.9	2.8, 1.9	2.3, 1.8	2.5, 1.9
	SD, SE	1568.00, 905.29	628.25, 362.72	1096.11, 447.48	2.89, 1.67	1.69, 0.84	2.06, 0.78
	MEDIAN	4054.9	3105.7	3123.9	1.1	2.1	1.1
	MIN, MAX	1399.7, 4172.4	2036.2, 3142.1	1399.7, 4172.4	1.1, 6.1	0.9, 4.2	0.9, 6.1
	5%, 95%	1399.7, 4172.4	2036.2, 3142.1	1399.7, 4172.4	1.1, 6.1	0.9, 4.2	0.9, 6.1
	BLQ Values Included	0	0	0	0	0	0

PM3003537958

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 379 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	3.3, 3.3	NA, NA	3.3, 3.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	3.3	NA	3.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	3.3, 3.3	NA, NA	3.3, 3.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	3	3	6	2	4	6
	MEAN, GEO MEAN	3306.4, 2593.2	2926.8, 2787.9	3116.6, 2688.7	3.3, 2.5	1.8, 1.7	2.3, 1.9
	SD, SE	2461.20, 1420.97	1142.28, 659.50	1728.63, 705.71	2.90, 2.05	0.70, 0.35	1.59, 0.65
	MEDIAN	3087.0	2575.4	2831.2	3.3	1.7	1.7
	MIN, MAX	962.3, 5870.0	2001.5, 4203.5	962.3, 5870.0	1.2, 5.3	1.2, 2.7	1.2, 5.3
	5%, 95%	962.3, 5870.0	2001.5, 4203.5	962.3, 5870.0	1.2, 5.3	1.2, 2.7	1.2, 5.3
	BLQ Values Included	0	0	0	0	0	0

PM3003537959

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 380 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.4, 2.4	NA, NA	2.4, 2.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.4	NA	2.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.4, 2.4	NA, NA	2.4, 2.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	0	NA	0
Caucasian	N	2	3	5	1	3	4
	MEAN, GEO MEAN	1564.6, 1348.2	2315.1, 2019.8	2014.9, 1718.2	1.3, 1.3	2.3, 2.2	2.1, 1.9
	SD, SE	1122.74, 793.90	1520.84, 878.06	1280.85, 572.81	NA, NA	0.90, 0.52	0.90, 0.45
	MEDIAN	1564.6	1702.9	1702.9	1.3	2.4	1.9
	MIN, MAX	770.7, 2358.5	1195.7, 4046.6	770.7, 4046.6	1.3, 1.3	1.4, 3.2	1.3, 3.2
	5%, 95%	770.7, 2358.5	1195.7, 4046.6	770.7, 4046.6	NA, NA	1.4, 3.2	1.3, 3.2
	BLQ Values Included	0	0	0	0	0	0

PM3003537960

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 381 of ?)

Lab: INBIFO
Biomarker: Free 3-hydroxycotinine (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	0	0	1	0	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	2.6, 2.6	NA, NA	2.6, 2.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	2.6	NA	2.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	2.6, 2.6	NA, NA	2.6, 2.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Caucasian	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3077.4, 2551.2	2667.7, 2555.4	2872.6, 2553.3	2.2, 1.8	2.1, 1.9	2.1, 1.8
	SD, SE	1990.01, 1148.93	992.49, 573.01	1424.22, 581.44	1.76, 1.02	0.95, 0.48	1.22, 0.46
	MEDIAN	3166.8	2270.0	2718.4	1.2	2.0	1.4
	MIN, MAX	1044.2, 5021.2	1935.8, 3797.4	1044.2, 5021.2	1.1, 4.2	1.1, 3.1	1.1, 4.2
	5%, 95%	1044.2, 5021.2	1935.8, 3797.4	1044.2, 5021.2	1.1, 4.2	1.1, 3.1	1.1, 4.2

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537961

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 382 of ?)

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1136.830, 1136.830	1136.830, 1136.830	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	1136.830	1136.830	0.000	0.000	0.000
	MIN, MAX	NA, NA	1136.826, 1136.826	1136.826, 1136.826	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	26	32	58
	MEAN, GEO MEAN	3185.830, 1315.050	3054.140, 1569.190	3106.820, 1462.120	3.628, NA	0.559, NA	1.935, NA
	SD, SE	4046.8000, 953.8390	3889.1000, 748.4570	3907.5700, 582.5060	5.9705, 1.1709	1.5688, 0.2773	4.3982, 0.5775
	MEDIAN	1437.370	1483.920	1476.520	0.000	0.000	0.000
	MIN, MAX	17.879, 12968.078	59.184, 17624.502	17.879, 17624.502	0.000, 22.811	0.000, 6.782	0.000, 22.811
	5%, 95%	17.879, 12968.100	212.693, 10892.300	109.121, 11547.000	0.000, 18.495	0.000, 4.932	0.000, 10.481
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1662.910, 483.021	1662.910, 483.021	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	2523.5500, 1456.9700	2523.5500, 1456.9700	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	344.624	344.624	0.000	NA	0.000
	MIN, MAX	NA, NA	71.514, 4572.581	71.514, 4572.581	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	71.514, 4572.580	71.514, 4572.580	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537962

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 383 of ?)

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4648.410, 4648.410	4648.410, 4648.410	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	4648.410	4648.410	0.000	0.000	0.000
	MIN, MAX	NA, NA	4648.410, 4648.410	4648.410, 4648.410	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	27	44	27	32	59
	MEAN, GEO MEAN	3220.380, 1984.940	3552.000, 1735.500	3423.870, 1827.920	5.549, NA	0.385, NA	2.748, NA
	SD, SE	3208.1800, 778.0980	5022.3900, 966.5590	4371.3100, 659.0000	19.0365, 3.6636	1.7837, 0.3153	13.0722, 1.7019
	MEDIAN	1499.950	1458.640	1479.290	0.000	0.000	0.000
	MIN, MAX	330.444, 10055.115	68.432, 25269.102	68.432, 25269.102	0.000, 99.257	0.000, 9.864	0.000, 99.257
	5%, 95%	330.444, 10055.100	106.038, 8746.290	330.444, 9456.490	0.000, 11.714	0.000, 2.466	0.000, 9.864
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.233, 1.233	1.233, 1.233
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.233	1.233
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.233, 1.233	1.233, 1.233
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3538.710, 667.894	3538.710, 667.894	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	5817.1900, 3358.5600	5817.1900, 3358.5600	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	239.202	239.202	0.000	NA	0.000
	MIN, MAX	NA, NA	121.451, 10255.478	121.451, 10255.478	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	121.451, 10255.500	121.451, 10255.500	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 384 of ?)

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4997.350, 4997.350	4997.350, 4997.350	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	4997.350	4997.350	0.000	0.000	0.000
	MIN, MAX	NA, NA	4997.349, 4997.349	4997.349, 4997.349	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	16	25	41	28	33	61
	MEAN, GEO MEAN	2390.020, 1334.460	3082.250, 1741.560	2812.110, 1569.690	2.774, NA	0.187, NA	1.375, NA
	SD, SE	1832.9400, 458.2350	2726.5200, 545.3030	2416.0100, 377.3170	5.9050, 1.1159	0.8081, 0.1407	4.2107, 0.5391
	MEDIAN	2286.600	2594.230	2594.230	0.000	0.000	0.000
	MIN, MAX	27.126, 5382.662	17.879, 8494.754	17.879, 8494.754	0.000, 28.976	0.000, 4.316	0.000, 28.976
	5%, 95%	27.126, 5382.660	130.698, 8343.710	130.698, 8015.730	0.000, 11.714	0.000, 1.850	0.000, 6.165
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.466, 2.466	2.466, 2.466
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.466	2.466
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.466, 2.466	2.466, 2.466
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1933.550, 297.303	1933.550, 297.303	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	3002.2000, 1733.3200	3002.2000, 1733.3200	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	395.177	395.177	0.000	NA	0.000
	MIN, MAX	NA, NA	12.330, 5393.142	12.330, 5393.142	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	12.330, 5393.140	12.330, 5393.140	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537964

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 385 of 7)

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3594.200, 3594.200	3594.200, 3594.200	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	3594.200	3594.200	0.000	0.000	0.000
	MIN, MAX	NA, NA	3594.200, 3594.200	3594.200, 3594.200	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2837.220, 1507.000	3099.230, 1790.530	2996.710, 1673.730	3.952, NA	0.380, NA	2.020, NA
	SD, SE	2855.8900, 673.1400	3448.8300, 651.7680	3199.1500, 471.6890	7.7433, 1.4634	1.1593, 0.2018	5.5606, 0.7120
	MEDIAN	1684.180	1332.880	1558.720	0.514	0.000	0.000
	MIN, MAX	22.503, 9135.910	98.640, 14522.700	22.503, 14522.700	0.000, 36.579	0.000, 5.549	0.000, 36.579
	5%, 95%	22.503, 9135.910	401.958, 11621.800	219.783, 9135.910	0.000, 19.112	0.000, 3.699	0.000, 7.707
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.233, 1.233	1.233, 1.233
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.233	1.233
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.233, 1.233	1.233, 1.233
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2378.390, 531.948	2378.390, 531.948	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	3779.8100, 2182.2800	3779.8100, 2182.2800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	326.334	326.334	0.000	NA	0.000
	MIN, MAX	NA, NA	68.432, 6740.400	68.432, 6740.400	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	68.432, 6740.400	68.432, 6740.400	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537965

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 386 of ?)

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1455.140, 1455.140	1455.140, 1455.140	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	1455.140	1455.140	0.000	0.000	0.000
	MIN, MAX	NA, NA	1455.137, 1455.137	1455.137, 1455.137	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	26	32	58
	MEAN, GEO MEAN	4026.810, 2152.390	4258.090, 2652.720	4165.580, 2439.970	5.629, NA	1.320, NA	3.252, NA
	SD, SE	3521.3800, 829.9970	4383.0300, 843.5140	4019.4500, 599.1850	9.1916, 1.8026	4.3595, 0.7706	7.2155, 0.9474
	MEDIAN	3048.350	2809.710	2809.710	0.000	0.000	0.000
	MIN, MAX	25.209, 10788.304	162.756, 22030.628	25.209, 22030.628	0.000, 29.594	0.000, 22.042	0.000, 29.594
	5%, 95%	25.209, 10788.300	185.043, 9928.730	162.756, 10045.900	0.000, 29.242	0.000, 11.235	0.000, 22.379
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3973.420, 1058.220	3973.420, 1058.220	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	6262.6800, 3615.7600	6262.6800, 3615.7600	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	510.044	510.044	0.000	NA	0.000
	MIN, MAX	NA, NA	207.391, 11202.823	207.391, 11202.823	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	207.391, 11202.800	207.391, 11202.800	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537966

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	6647.230, 6647.230	6647.230, 6647.230	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	6647.230	6647.230	0.000	0.000	0.000
	MIN, MAX	NA, NA	6647.226, 6647.226	6647.226, 6647.226	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	27	44	27	32	59
	MEAN, GEO MEAN	4025.200, 2885.680	4410.420, 2851.750	4261.580, 2864.820	13.755, NA	0.815, NA	6.737, NA
	SD, SE	3025.1900, 733.7160	4456.4800, 857.6500	3930.6200, 592.5640	54.1292, 10.4172	3.8893, 0.6875	36.9296, 4.8078
	MEDIAN	3547.290	3511.090	3529.190	0.000	0.000	0.000
	MIN, MAX	461.543, 9872.580	193.519, 22489.501	193.519, 22489.501	0.000, 282.882	0.000, 21.701	0.000, 282.882
	5%, 95%	461.543, 9872.580	294.258, 11807.500	461.543, 9872.580	0.000, 23.674	0.000, 4.389	0.000, 21.701
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.404, 2.404	2.404, 2.404
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.404	2.404
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.404, 2.404	2.404, 2.404
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	5828.390, 1050.450	5828.390, 1050.450	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	9607.5200, 5546.9000	9607.5200, 5546.9000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	386.311	386.311	0.000	NA	0.000
	MIN, MAX	NA, NA	177.318, 16921.539	177.318, 16921.539	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	177.318, 16921.500	177.318, 16921.500	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537967

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	6671.460, 6671.460	6671.460, 6671.460	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	6671.460	6671.460	0.000	0.000	0.000
	MIN, MAX	NA, NA	6671.461, 6671.461	6671.461, 6671.461	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	16	25	41	28	33	61
	MEAN, GEO MEAN	4351.610, 2285.070	4700.410, 3190.940	4564.300, 2801.090	4.859, NA	0.328, NA	2.408, NA
	SD, SE	3671.9000, 917.9750	3237.7400, 647.5490	3372.7600, 526.7370	8.7946, 1.6620	1.4756, 0.2569	6.4147, 0.8213
	MEDIAN	3945.800	4005.330	4005.330	0.000	0.000	0.000
	MIN, MAX	28.428, 11461.291	52.296, 12487.288	28.428, 12487.288	0.000, 37.669	0.000, 8.114	0.000, 37.669
	5%, 95%	28.428, 11461.300	243.098, 10420.500	243.098, 10485.800	0.000, 21.208	0.000, 2.720	0.000, 14.303
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	4.279, 4.279	4.279, 4.279
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	4.279	4.279
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	4.279, 4.279	4.279, 4.279
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	1966.130, 321.454	1966.130, 321.454	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	3093.7300, 1786.1700	3093.7300, 1786.1700	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	347.756	347.756	0.000	NA	0.000
	MIN, MAX	NA, NA	17.262, 5533.364	17.262, 5533.364	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	17.262, 5533.360	17.262, 5533.360	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Nicotine Glurunonide (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4924.610, 4924.610	4924.610, 4924.610	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	4924.610	4924.610	0.000	0.000	0.000
	MIN, MAX	NA, NA	4924.610, 4924.610	4924.610, 4924.610	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	3965.130, 2293.940	4306.410, 3071.920	4172.870, 2740.200	8.000, NA	0.822, NA	4.117, NA
	SD, SE	3288.3000, 775.0590	3529.9400, 667.0950	3404.3400, 501.9420	19.9342, 3.7672	2.6720, 0.4651	13.9869, 1.7908
	MEDIAN	3242.430	2982.790	3084.910	0.702	0.000	0.000
	MIN, MAX	26.819, 10353.300	199.791, 15441.800	26.819, 15441.800	0.000, 104.041	0.000, 11.885	0.000, 104.041
	5%, 95%	26.819, 10353.300	535.807, 12852.600	373.255, 10353.300	0.000, 21.634	0.000, 10.052	0.000, 18.618
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	2.228, 2.228	2.228, 2.228
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	2.228	2.228
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	2.228, 2.228	2.228, 2.228
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3922.630, 854.261	3922.630, 854.261	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	6320.5700, 3649.1800	6320.5700, 3649.1800	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	414.704	414.704	0.000	NA	0.000
	MIN, MAX	NA, NA	133.990, 11219.200	133.990, 11219.200	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	133.990, 11219.200	133.990, 11219.200	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	0.995, 0.995	0.995, 0.995	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	0.995	0.995	0.000	0.000	0.000
	MIN, MAX	NA, NA	0.995, 0.995	0.995, 0.995	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	26	32	58
	MEAN, GEO MEAN	2.667, 1.629	3.393, 2.360	3.103, 2.035	0.003, NA	0.001, NA	0.002, NA
	SD, SE	1.8782, 0.4427	2.5665, 0.4939	2.3205, 0.3459	0.0063, 0.0012	0.0032, 0.0006	0.0049, 0.0006
	MEDIAN	2.644	3.163	2.840	0.000	0.000	0.000
	MIN, MAX	0.024, 7.058	0.135, 12.113	0.024, 12.113	0.000, 0.023	0.000, 0.016	0.000, 0.023
	5%, 95%	0.024, 7.058	0.307, 7.068	0.135, 7.058	0.000, 0.021	0.000, 0.008	0.000, 0.016
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.000	0.000
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2.437, 0.748	2.437, 0.748	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	3.7742, 2.1791	3.7742, 2.1791	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.329	0.329	0.000	NA	0.000
	MIN, MAX	NA, NA	0.187, 6.794	0.187, 6.794	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.187, 6.794	0.187, 6.794	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4.548, 4.548	4.548, 4.548	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	4.548	4.548	0.000	0.000	0.000
	MIN, MAX	NA, NA	4.548, 4.548	4.548, 4.548	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	27	44	27	32	59
	MEAN, GEO MEAN	2.720, 2.069	3.418, 2.248	3.149, 2.177	0.012, NA	0.001, NA	0.006, NA
	SD, SE	1.8726, 0.4542	3.3989, 0.6541	2.8997, 0.4371	0.0517, 0.0100	0.0029, 0.0005	0.0352, 0.0046
	MEDIAN	2.323	2.864	2.471	0.000	0.000	0.000
	MIN, MAX	0.298, 6.734	0.193, 17.646	0.193, 17.646	0.000, 0.270	0.000, 0.016	0.000, 0.270
	5%, 95%	0.298, 6.734	0.222, 6.805	0.298, 6.734	0.000, 0.017	0.000, 0.004	0.000, 0.016
	BLQ Values Included	0	0	0	20	30	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	4.114, 0.935	4.114, 0.935	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	6.6006, 3.8108	6.6006, 3.8108	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.456	0.456	0.000	NA	0.000
	MIN, MAX	NA, NA	0.153, 11.734	0.153, 11.734	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.153, 11.734	0.153, 11.734	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4.017, 4.017	4.017, 4.017	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	4.017	4.017	0.000	0.000	0.000
	MIN, MAX	NA, NA	4.017, 4.017	4.017, 4.017	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	16	25	41	28	33	61
	MEAN, GEO MEAN	2.776, 1.558	3.730, 2.627	3.358, 2.142	0.002, NA	0.000, NA	0.001, NA
	SD, SE	2.1773, 0.5443	2.5329, 0.5066	2.4184, 0.3777	0.0046, 0.0009	0.0015, 0.0003	0.0035, 0.0004
	MEDIAN	2.549	3.179	2.840	0.000	0.000	0.000
	MIN, MAX	0.025, 6.372	0.056, 10.645	0.025, 10.645	0.000, 0.021	0.000, 0.008	0.000, 0.021
	5%, 95%	0.025, 6.372	0.242, 8.031	0.226, 7.486	0.000, 0.011	0.000, 0.004	0.000, 0.008
	BLQ Values Included	0	0	0	21	32	53
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.006	0.006
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.006, 0.006	0.006, 0.006
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.359, 0.411	3.359, 0.411	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	5.4938, 3.1718	5.4938, 3.1718	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.358	0.358	0.000	NA	0.000
	MIN, MAX	NA, NA	0.020, 9.700	0.020, 9.700	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.020, 9.700	0.020, 9.700	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Nicotine Gluruonide (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.187, 3.187	3.187, 3.187	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	3.187	3.187	0.000	0.000	0.000
	MIN, MAX	NA, NA	3.187, 3.187	3.187, 3.187	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	2.612, 1.659	3.513, 2.619	3.160, 2.191	0.006, NA	0.001, NA	0.003, NA
	SD, SE	1.9175, 0.4520	2.4597, 0.4648	2.2840, 0.3368	0.0182, 0.0034	0.0021, 0.0004	0.0126, 0.0016
	MEDIAN	2.521	2.985	2.648	0.001	0.000	0.000
	MIN, MAX	0.025, 6.721	0.190, 10.339	0.025, 10.339	0.000, 0.097	0.000, 0.009	0.000, 0.097
	5%, 95%	0.025, 6.721	0.380, 8.383	0.374, 7.495	0.000, 0.013	0.000, 0.008	0.000, 0.009
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.003	0.003
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.003, 0.003	0.003, 0.003
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.303, 0.755	3.303, 0.755	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	5.2893, 3.0538	5.2893, 3.0538	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.381	0.381	0.000	NA	0.000
	MIN, MAX	NA, NA	0.120, 9.409	0.120, 9.409	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.120, 9.409	0.120, 9.409	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

PM3003537973

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	9129.370, 9129.370	9129.370, 9129.370	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	9129.370	9129.370	0.000	0.000	0.000
	MIN, MAX	NA, NA	9129.373, 9129.373	9129.373, 9129.373	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	12775.700, 5928.170	12304.200, 6810.690	12488.700, 6450.700	13.276, NA	3.130, NA	7.787, NA
	SD, SE	15906.0000, 3749.0900	13158.2000, 2486.6700	14125.0000, 2082.6200	25.6140, 4.8406	6.9304, 1.2064	18.6235, 2.3845
	MEDIAN	6149.150	6802.620	6149.150	4.257	0.000	0.000
	MIN, MAX	71.505, 58435.475	103.285, 57183.003	71.505, 58435.475	0.000, 121.445	0.000, 31.780	0.000, 121.445
	5%, 95%	71.505, 58435.500	1445.420, 41739.100	1334.760, 44549.900	0.000, 49.373	0.000, 23.268	0.000, 38.023
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	23.268, 23.268	23.268, 23.268
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	23.268	23.268
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	23.268, 23.268	23.268, 23.268
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	9550.460, 2618.590	9550.460, 2618.590	1.703, 1.703	NA, NA	1.703, 1.703
	SD, SE	NA, NA	13241.6000, 7645.0500	13241.6000, 7645.0500	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3756.280	3756.280	1.703	NA	1.703
	MIN, MAX	NA, NA	193.518, 24701.573	193.518, 24701.573	1.703, 1.703	NA, NA	1.703, 1.703
	5%, 95%	NA, NA	193.518, 24701.600	193.518, 24701.600	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12659.800, 12659.800	12659.800, 12659.800	0.000, NA	1.135, NA	0.757, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.6051, 1.1350	1.3106, 0.7567
	MEDIAN	NA	12659.800	12659.800	0.000	1.135	0.000
	MIN, MAX	NA, NA	12659.790, 12659.790	12659.790, 12659.790	0.000, 0.000	0.000, 2.270	0.000, 2.270
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 2.270	0.000, 2.270
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	12429.200, 6666.940	15551.100, 8953.100	14302.300, 7957.100	15.181, NA	3.904, NA	9.080, NA
	SD, SE	14018.0000, 3304.0700	16915.0000, 3255.2900	15728.4000, 2344.6500	25.5587, 4.8301	6.9963, 1.2179	18.7662, 2.4028
	MEDIAN	8346.790	6741.330	7567.610	3.122	0.000	1.135
	MIN, MAX	73.775, 60546.008	286.588, 77152.193	73.775, 77152.193	0.000, 92.503	0.000, 24.970	0.000, 92.503
	5%, 95%	73.775, 60546.000	1943.690, 42264.000	1502.740, 42264.000	0.000, 71.505	0.000, 20.430	0.000, 57.318
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	17.025, 17.025	17.025, 17.025
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	17.025	17.025
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	17.025, 17.025	17.025, 17.025
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	12040.800, 2742.200	12040.800, 2742.200	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	18905.1000, 10914.8000	18905.1000, 10914.8000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1962.420	1962.420	0.000	NA	0.000
	MIN, MAX	NA, NA	310.423, 33849.673	310.423, 33849.673	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	310.423, 33849.700	310.423, 33849.700	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537975

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 396 of ?)

Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	13333.400, 13333.400	13333.400, 13333.400	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	13333.400	13333.400	0.000	0.000	0.000
	MIN, MAX	NA, NA	13333.413, 13333.413	13333.413, 13333.413	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	9575.360, 5758.280	12541.500, 8280.000	11340.900, 7147.990	9.567, NA	1.943, NA	5.443, NA
	SD, SE	7119.6800, 1726.7800	10322.0000, 2064.4000	9182.5900, 1416.9000	16.4295, 3.1049	4.8051, 0.8365	12.1841, 1.5600
	MEDIAN	8817.820	8595.360	8706.590	3.405	0.000	0.000
	MIN, MAX	81.153, 23770.305	900.623, 37456.135	81.153, 37456.135	0.000, 78.883	0.000, 19.863	0.000, 78.883
	5%, 95%	81.153, 23770.300	1770.600, 29846.500	900.623, 27258.700	0.000, 36.320	0.000, 14.755	0.000, 22.133
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	28.943, 28.943	28.943, 28.943
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	28.943	28.943
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	28.943, 28.943	28.943, 28.943
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	8542.580, 2141.040	8542.580, 2141.040	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	12390.4000, 7153.6300	12390.4000, 7153.6300	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2692.790	2692.790	0.000	NA	0.000
	MIN, MAX	NA, NA	160.035, 22774.910	160.035, 22774.910	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	160.035, 22774.900	160.035, 22774.900	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11707.500, 11707.500	11707.500, 11707.500	0.000, NA	0.379, NA	0.252, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.5353, 0.3785	0.4371, 0.2523
	MEDIAN	NA	11707.500	11707.500	0.000	0.379	0.000
	MIN, MAX	NA, NA	11707.500, 11707.500	11707.500, 11707.500	0.000, 0.000	0.000, 0.757	0.000, 0.757
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.757	0.000, 0.757
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	11720.700, 6790.710	13058.200, 8110.420	12534.900, 7565.940	12.674, NA	2.992, NA	7.437, NA
	SD, SE	10966.1000, 2584.7400	12415.8000, 2346.3600	11762.5000, 1734.2800	18.4095, 3.4791	5.2941, 0.9216	13.8247, 1.7701
	MEDIAN	9090.310	7428.200	8028.620	4.824	0.000	1.135
	MIN, MAX	75.478, 44996.300	430.165, 53864.600	75.478, 53864.600	0.000, 74.910	0.000, 23.268	0.000, 74.910
	5%, 95%	75.478, 44996.300	1947.850, 31626.000	1197.990, 31626.000	0.000, 52.400	0.000, 15.134	0.000, 33.293
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	23.079, 23.079	23.079, 23.079
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	23.079	23.079
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	23.079, 23.079	23.079, 23.079
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	10044.600, 2562.300	10044.600, 2562.300	0.568, 0.568	NA, NA	0.568, 0.568
	SD, SE	NA, NA	14834.2000, 8564.5500	14834.2000, 8564.5500	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2803.830	2803.830	0.568	NA	0.568
	MIN, MAX	NA, NA	221.325, 27108.700	221.325, 27108.700	0.568, 0.568	NA, NA	0.568, 0.568
	5%, 95%	NA, NA	221.325, 27108.700	221.325, 27108.700	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	11685.600, 11685.600	11685.600, 11685.600	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	11685.600	11685.600	0.000	0.000	0.000
	MIN, MAX	NA, NA	11685.597, 11685.597	11685.597, 11685.597	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	17099.600, 9702.850	17610.400, 11772.300	17410.500, 10914.500	19.319, NA	6.685, NA	12.484, NA
	SD, SE	16437.9000, 3874.4400	13032.5000, 2462.9200	14284.6000, 2106.1400	31.8831, 6.0253	17.8234, 3.1027	25.8295, 3.3071
	MEDIAN	14284.800	13807.000	13807.000	4.169	0.000	0.000
	MIN, MAX	100.822, 68661.683	284.034, 52173.823	100.822, 68661.683	0.000, 106.872	0.000, 75.621	0.000, 106.872
	5%, 95%	100.822, 68661.700	1350.340, 40028.100	1350.340, 40028.100	0.000, 106.084	0.000, 72.395	0.000, 75.621
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	31.877, 31.877	31.877, 31.877
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	31.877	31.877
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	31.877, 31.877	31.877, 31.877
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	22213.100, 5736.890	22213.100, 5736.890	1.379, 1.379	NA, NA	1.379, 1.379
	SD, SE	NA, NA	33267.7000, 19207.1000	33267.7000, 19207.1000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	5559.300	5559.300	1.379	NA	1.379
	MIN, MAX	NA, NA	561.202, 60518.854	561.202, 60518.854	1.379, 1.379	NA, NA	1.379, 1.379
	5%, 95%	NA, NA	561.202, 60518.900	561.202, 60518.900	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

PM3003537978

Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 399 of ?)

Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	18103.500, 18103.500	18103.500, 18103.500	0.000, NA	0.749, NA	0.499, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.0592, 0.7490	0.8649, 0.4993
	MEDIAN	NA	18103.500	18103.500	0.000	0.749	0.000
	MIN, MAX	NA, NA	18103.500, 18103.500	18103.500, 18103.500	0.000, 0.000	0.000, 1.498	0.000, 1.498
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 1.498	0.000, 1.498
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	15578.800, 9437.530	19738.500, 14711.700	18074.600, 12318.000	24.654, NA	8.254, NA	15.782, NA
	SD, SE	12680.2000, 2988.7600	14276.3000, 2747.4800	13667.7000, 2037.4600	44.9218, 8.4894	15.1780, 2.6421	33.1490, 4.2443
	MEDIAN	14129.700	14973.800	14973.800	4.055	0.000	1.396
	MIN, MAX	66.398, 54491.407	523.023, 68665.452	66.398, 68665.452	0.000, 203.789	0.000, 54.934	0.000, 203.789
	5%, 95%	66.398, 54491.400	3575.520, 40276.000	2719.960, 40276.000	0.000, 103.001	0.000, 44.129	0.000, 73.080
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	33.199, 33.199	33.199, 33.199
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	33.199	33.199
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	33.199, 33.199	33.199, 33.199
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	19824.800, 4312.900	19824.800, 4312.900	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	31230.0000, 18030.6000	31230.0000, 18030.6000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3169.300	3169.300	0.000	NA	0.000
	MIN, MAX	NA, NA	453.218, 55851.960	453.218, 55851.960	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	453.218, 55852.000	453.218, 55852.000	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 400 of ?)

Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/24hr)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	17800.100, 17800.100	17800.100, 17800.100	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	17800.100	17800.100	0.000	0.000	0.000
	MIN, MAX	NA, NA	17800.106, 17800.106	17800.106, 17800.106	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	17262.700, 9735.880	19280.000, 15170.900	18463.500, 12677.700	16.671, NA	3.937, NA	9.782, NA
	SD, SE	13557.2000, 3288.1100	11832.4000, 2366.4800	12437.2000, 1919.1100	27.7821, 5.2503	10.6944, 1.8617	21.1959, 2.7139
	MEDIAN	14321.900	17401.000	16848.200	4.562	0.000	0.000
	MIN, MAX	85.048, 48342.568	1675.159, 48692.976	85.048, 48692.976	0.000, 105.328	0.000, 52.637	0.000, 105.328
	5%, 95%	85.048, 48342.600	3346.430, 37176.400	1675.160, 37176.400	0.000, 102.548	0.000, 27.739	0.000, 42.948
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	50.216, 50.216	50.216, 50.216
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	50.216	50.216
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	50.216, 50.216	50.216, 50.216
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	8653.590, 2314.960	8653.590, 2314.960	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	12787.3000, 7382.7600	12787.3000, 7382.7600	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2369.650	2369.650	0.000	NA	0.000
	MIN, MAX	NA, NA	224.049, 23367.058	224.049, 23367.058	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	224.049, 23367.100	224.049, 23367.100	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Glurunonide (nmol/24hr)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	15863.100, 15863.100	15863.100, 15863.100	0.000, NA	0.250, NA	0.166, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.3528, 0.2495	0.2881, 0.1663
	MEDIAN	NA	15863.100	15863.100	0.000	0.250	0.000
	MIN, MAX	NA, NA	15863.100, 15863.100	15863.100, 15863.100	0.000, 0.000	0.000, 0.499	0.000, 0.499
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.499	0.000, 0.499
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	16709.600, 10031.400	18288.700, 13743.000	17670.800, 12150.200	20.215, NA	6.292, NA	12.683, NA
	SD, SE	13467.5000, 3174.3200	12311.1000, 2326.5900	12651.7000, 1865.3900	29.9166, 5.6537	12.2713, 2.1362	23.0651, 2.9532
	MEDIAN	16733.600	15693.500	16175.200	6.685	0.000	2.217
	MIN, MAX	84.089, 57165.200	827.405, 46589.500	84.089, 57165.200	0.000, 104.966	0.000, 48.839	0.000, 104.966
	5%, 95%	84.089, 57165.200	3648.460, 42236.000	1859.720, 42236.000	0.000, 97.288	0.000, 42.815	0.000, 50.161
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	38.431, 38.431	38.431, 38.431
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	38.431	38.431
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	38.431, 38.431	38.431, 38.431
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	16897.200, 4143.460	16897.200, 4143.460	0.460, 0.460	NA, NA	0.460, 0.460
	SD, SE	NA, NA	25757.9000, 14871.4000	25757.9000, 14871.4000	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3699.420	3699.420	0.460	NA	0.460
	MIN, MAX	NA, NA	412.823, 46579.300	412.823, 46579.300	0.460, 0.460	NA, NA	0.460, 0.460
	5%, 95%	NA, NA	412.823, 46579.300	412.823, 46579.300	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	7.987, 7.987	7.987, 7.987	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	7.987	7.987	0.000	0.000	0.000
	MIN, MAX	NA, NA	7.987, 7.987	7.987, 7.987	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	11.128, 7.340	14.917, 10.592	13.434, 9.176	0.012, NA	0.005, NA	0.008, NA
	SD, SE	7.4252, 1.7501	9.5405, 1.8030	8.8847, 1.3100	0.0216, 0.0041	0.0129, 0.0022	0.0176, 0.0022
	MEDIAN	10.682	14.909	12.977	0.002	0.000	0.000
	MIN, MAX	0.095, 27.231	0.236, 37.108	0.095, 37.108	0.000, 0.075	0.000, 0.055	0.000, 0.075
	5%, 95%	0.095, 27.231	1.535, 33.762	1.495, 32.060	0.000, 0.066	0.000, 0.049	0.000, 0.055
	BLQ Values Included	0	0	0	17	29	46
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.036, 0.036	0.036, 0.036
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.036	0.036
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.036, 0.036	0.036, 0.036
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	13.598, 4.055	13.598, 4.055	0.001, 0.001	NA, NA	0.001, 0.001
	SD, SE	NA, NA	20.0692, 11.5869	20.0692, 11.5869	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.584	3.584	0.001	NA	0.001
	MIN, MAX	NA, NA	0.507, 36.704	0.507, 36.704	0.001, 0.001	NA, NA	0.001, 0.001
	5%, 95%	NA, NA	0.507, 36.704	0.507, 36.704	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	12.387, 12.387	12.387, 12.387	0.000, NA	0.001, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0007, 0.0005	0.0006, 0.0003
	MEDIAN	NA	12.387	12.387	0.000	0.001	0.000
	MIN, MAX	NA, NA	12.387, 12.387	12.387, 12.387	0.000, 0.000	0.000, 0.001	0.000, 0.001
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.001	0.000, 0.001
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	10.408, 6.935	15.401, 11.598	13.404, 9.441	0.017, NA	0.006, NA	0.011, NA
	SD, SE	6.8410, 1.6124	11.2610, 2.1672	9.9565, 1.4842	0.0382, 0.0072	0.0105, 0.0018	0.0273, 0.0035
	MEDIAN	10.268	13.819	11.760	0.003	0.000	0.001
	MIN, MAX	0.074, 26.176	0.522, 53.877	0.074, 53.877	0.000, 0.195	0.000, 0.039	0.000, 0.195
	5%, 95%	0.074, 26.176	2.801, 34.914	2.444, 34.082	0.000, 0.058	0.000, 0.026	0.000, 0.039
	BLQ Values Included	0	0	0	16	28	44
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.045, 0.045	0.045, 0.045
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.045	0.045
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.045, 0.045	0.045, 0.045
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	14.287, 3.843	14.287, 3.843	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	21.2346, 12.2598	21.2346, 12.2598	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.738	3.738	0.000	NA	0.000
	MIN, MAX	NA, NA	0.392, 38.730	0.392, 38.730	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.392, 38.730	0.392, 38.730	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.718, 10.718	10.718, 10.718	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	10.718	10.718	0.000	0.000	0.000
	MIN, MAX	NA, NA	10.718, 10.718	10.718, 10.718	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	11.268, 7.027	15.569, 12.491	13.828, 9.896	0.009, NA	0.003, NA	0.006, NA
	SD, SE	7.7146, 1.8711	10.1975, 2.0395	9.4160, 1.4529	0.0155, 0.0029	0.0088, 0.0015	0.0125, 0.0016
	MEDIAN	9.472	14.683	14.169	0.003	0.000	0.000
	MIN, MAX	0.075, 22.527	1.668, 49.743	0.075, 49.743	0.000, 0.060	0.000, 0.035	0.000, 0.060
	5%, 95%	0.075, 22.527	2.890, 34.847	1.863, 24.778	0.000, 0.057	0.000, 0.028	0.000, 0.028
	BLQ Values Included	0	0	0	16	31	47
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.067, 0.067	0.067, 0.067
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.067	0.067
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.067, 0.067	0.067, 0.067
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	14.554, 2.976	14.554, 2.976	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	22.8955, 13.2187	22.8955, 13.2187	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2.437	2.437	0.000	NA	0.000
	MIN, MAX	NA, NA	0.264, 40.962	0.264, 40.962	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.264, 40.962	0.264, 40.962	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001

TABLE 14.4-8
DESCRIPTIVE STATISTICS OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Cotinine Gluruonide (nmol/mg Creatin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	10.364, 10.364	10.364, 10.364	0.000, NA	0.000, NA	0.000, NA
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	NA	10.364	10.364	0.000	0.000	0.000
	MIN, MAX	NA, NA	10.364, 10.364	10.364, 10.364	0.000, 0.000	0.000, 0.000	0.000, 0.000
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	10.959, 7.253	15.142, 11.737	13.505, 9.722	0.013, NA	0.005, NA	0.008, NA
	SD, SE	7.0907, 1.6713	9.6698, 1.8274	8.9083, 1.3135	0.0213, 0.0040	0.0095, 0.0017	0.0164, 0.0021
	MEDIAN	11.094	15.291	13.028	0.003	0.000	0.002
	MIN, MAX	0.081, 23.794	0.809, 38.906	0.081, 38.906	0.000, 0.091	0.000, 0.038	0.000, 0.091
	5%, 95%	0.081, 23.794	2.438, 38.061	2.066, 34.230	0.000, 0.061	0.000, 0.036	0.000, 0.038
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.049, 0.049	0.049, 0.049
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.049	0.049
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.049, 0.049	0.049, 0.049
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	14.147, 3.659	14.147, 3.659	0.000, NA	NA, NA	0.000, NA
	SD, SE	NA, NA	21.3976, 12.3539	21.3976, 12.3539	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.253	3.253	0.000	NA	0.000
	MIN, MAX	NA, NA	0.388, 38.799	0.388, 38.799	0.000, 0.000	NA, NA	0.000, 0.000
	5%, 95%	NA, NA	0.388, 38.799	0.388, 38.799	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/fjnj0001